

2/25/03 8:56 am

Notification Tracking Sheet

=====  
Bp number: 03-052-52n  
=====

App number: 2003-241XRAB  
Received: 2/21/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 3/23/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.  
Address3:  
Address4:  
City/State/Zip: Chesterfield, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 3/20/03  
End movement: 3/20/04  
Begin release: 3/20/03  
End release: 3/20/04  
Acre: 4.00  
CBI status: CBI  
Fax: 636-737-7085  
=====

- |  | Initial        | Date         |
|--|----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ <i>ajd</i> ] | [ 2/25/03 ]  |
| 2. <input type="checkbox"/> Review by biotechnologist                          | [ <i>KL</i> ]* | [ 02-25-03 ] |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ <i>KL</i> ]  | [ 2/27/03 ]* |
| 4. <input type="checkbox"/> State response                                     |                |              |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MN	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MN	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Release	* *MN	*	1*NER *

- |  |                |              |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajd</i> ] | [ 2/25/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KL</i> ]  | [ 3/28/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KL</i> ]  | [ 4/1/03 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |              |



MONSANTO



*CONFIDENTIAL*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-241XRAB

Permit Unit

February 18, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-52n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-241XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 20, 2003 - March 20, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-241XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

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# CONFIDENTIAL

**Monsanto Reference ID**  
2003-241XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

1000 lbs Ship up to \_1,000\_pounds wheat seed to and from each location.

### ORIGIN:

KS, MN, MO

### DESTINATION:

KS, MN, MO

### Ship From/Ship To:

KS

\* (b) (4) Geary County/Province, KS, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

MN

\* (b) (4) Polk County/Province, MN, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

MO

\* (b) (4) St. Louis County/Province, MO,  
(b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)  
]-CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-241XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN(1)

MN

(b) (4)

Polk County/Province, MN, 56716, USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)

CO

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

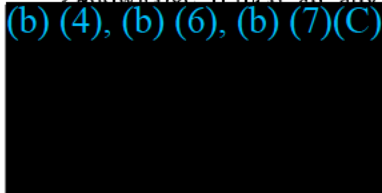
**Monsanto Reference ID**  
2003-241XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (4), (b) (6), (b) (7)(C)



Monsanto Company

February 18, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-241XRAB

Permit Unit

February 18, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-52n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-241XRAB

**3. Application/Responsible Party**

(b) (4), (b) (6), (b) (7)(C)

Phone

(b) (4), (b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (4), (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 20, 2003 - March 20, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

### **Monsanto Reference ID**

2003-241XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMOVa/I2 -- [ CBI Deleted ]

***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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## *CBI-DELETED*

**Monsanto Reference ID**  
2003-241XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction**      Interstate Movement and Release

1000 lbs Ship up to \_1,000\_pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MN, MO

#### **DESTINATION:**

KS, MN, MO

#### **Ship From/Ship To:**

**KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-241XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN(1)

MN

[ CBI Deleted ] -- Polk County/Province, MN, USA, 4 acres.



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*CBI-DELETED*

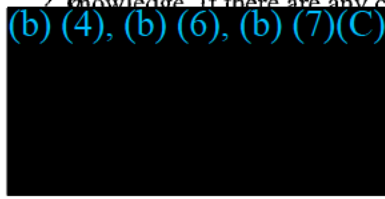
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**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (4), (b) (6), (b) (7)(C)



Monsanto Company

February 18, 2003



MONSANTO



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**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



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**Monsanto Reference ID**  
2003-241XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

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*CBI*

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## *CBI-DELETED*

**Monsanto Reference ID**  
2003-241XRAB

### **7. Mode of Transformation**

PV-TXGT10 GENE OF INTEREST CMoVa/I2 CTP2-CP4 ; NOS 3'

Disarmed Agrobacterium tumefaciens

PV-TXGT10 GENE OF INTEREST CMP3/I5 CTP2-CP4 NOS 3'

Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

1000 lbs Ship up to \_1,000\_pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MN, MO

#### **DESTINATION:**

KS, MN, MO

#### **Ship From/Ship To:**

**KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-241XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN(1)

**MN**

[ CBI Deleted ] -- Polk County/Province, MN, USA, 4 acres.



MONSANTO



*CBI-DELETED*

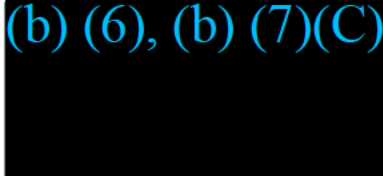
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**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 18, 2003



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

February 25, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010504



file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 25, 2003

Dear Dr. Hanks:


Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010505



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
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Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010506





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

February 25, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010507





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 25, 2003

Dear Dr. Hanks:

Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination *with the attached additional conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-26-03

State: MN

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-52n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-52n	Applicant #:	2003-241XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4





March 28, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 28, 2003.

Interstate movement and Release  
Notification no. 03-052-52n (2003-241XRAB)  
Regulated article - Wheat  
Destinations - Kansas, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concurs with APHIS determination; with the (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 03-052-52n

OR120018\_BR\_010510





## Minnesota Department of Agriculture

(651) 296-1277

March 26, 2003

Ms. Mary Jackson  
Biotechnology Program Operations - Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 03-052-52n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
  - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains) should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2003.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.  
State Biotechnologist



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA # [REDACTED] Monsanto #2003-241XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147315828	Polk	MN

Polk County/MN (2147315828)

(b) (4)

aid  
2/18/04



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



***CBI-DELETED***

**2003 Wheat Field Test Report**  
**USDA #03-052-52n                      Monsanto #2003-241XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147315828	Polk	MN

**Polk County/MN (2147315828)**

**Planting Date:** 05/27/2003

**Harvest Date:** 08/14/2003

**Destruct Date:** 08/29/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]



2/25/03 8:56 am

Notification Tracking Sheet

=====  
Bp number: 03-052-59n  
=====

App number: 2003-250XRAB  
Received: 2/21/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 3/23/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.  
Address3:  
Address4:  
City/State/Zip: Chesterfield, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 3/22/03  
End movement: 3/22/04  
Begin release: 3/22/03  
End release: 3/22/04  
Acre: 50.00  
CBI status: CBI  
Fax: 636-737-7085  
=====

- |  | Initial         | Date         |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]  | [ 2/25/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>gmc</i> ]* | [ 2/26/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLn</i> ]  | [ 2/27/03 ]* |
| 4. [ ] State response  |                 |              |

	O/d	Loc	Site	Reg		
Interstate	*Dest*ID	*	*WR	*	[ ]	[ ]
Interstate	*Dest*MN	*	*NER	*	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*ND	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*SD	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*WA	*	*WR	*	[ ]	[ ]
Interstate	*Orig*ID	*	*WR	*		
Interstate	*Orig*MN	*	*NER	*		
Interstate	*Orig*MO	*	*SCR	*		
Interstate	*Orig*ND	*	*SCR	*		
Interstate	*Orig*SD	*	*SCR	*		
Interstate	*Orig*WA	*	*WR	*		
Release	*ID	*	1*WR	*	[ ]	[ ]
Release	*MN	*	1*NER	*	[ ]	[ ]
Release	*ND	*	1*SCR	*	[ ]	[ ]
Release	*SD	*	1*SCR	*	[ ]	[ ]
Release	*WA	*	1*WR	*	[ ]	[ ]

- |   |                |              |
|---|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database  | [ <i>ajd</i> ] | [ 2/26/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw  | [ <i>KLn</i> ] | [ 3/31/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database   | [ <i>KLn</i> ] | [ 4/3/03 ]   |
| 8. [ ] If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |              |

OR120018\_BR\_010517



MONSANTO



*CONFIDENTIAL*

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-250XRAB

February 20, 2003

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-59n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-250XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 22, 2003 - March 22, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-250XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-250XRAB

### 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### 8. Introduction Interstate Movement and Release

10,000 pounds Ship up to 10,000 pounds wheat seed to and from each location.

#### ORIGIN:

ID, MN, MO, ND, SD, WA

#### DESTINATION:

ID, MN, MO, ND, SD, WA

#### Ship From/Ship To:

##### ID

\* [REDACTED] (b) (4) Fremont County/Province, ID, (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) ID, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
]-CBI

##### MN

\* [REDACTED] (b) (4) Wilkin County/Province, MN, (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) MN [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
]-CBI

##### MO

\* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MO [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
]-CBI

\* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.



*CONFIDENTIAL*

Monsanto Reference ID  
2003-250XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)  
U.S.A. (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
MO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

ND

\* (b) (4) McHenry County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

\* (b) (4) Marshall  
County/Province, SD, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

\* (b) (4) Grant County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-250XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1), MN(1), ND(1), SD(1), WA(1)

**ID**

(b) (4) Fremont County/Province, ID, (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] -CBI

**MN**

(b) (4) Wilkin County/Province, MN (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C)

] -CBI

**ND**

(b) (4) McHenry County/Province, ND, (b) (4) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

**SD**

(b) (4) Marshall County/Province, SD, (b) (4) 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD

] -CBI

**WA**



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-250XRAB

(b) (4) Grant County/Province, WA, (b) (4) USA, 10  
acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-250XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 20, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

February 20, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-59n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-250XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 22, 2003 - March 22, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds Ship up to 10,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

ID, MN, MO, ND, SD, WA

#### **DESTINATION:**

ID, MN, MO, ND, SD, WA

#### **Ship From/Ship To:**

##### **ID**

[ CBI Deleted ] -- \*Fremont County/Province, ID, USA

##### **MN**

[ CBI Deleted ] -- \*Wilkin County/Province, MN, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **ND**

[ CBI Deleted ] -- \*McHenry County/Province, ND, USA

##### **SD**

[ CBI Deleted ] -- \*Marshall County/Province, SD

##### **WA**

[ CBI Deleted ] -- \*Grant County/Province, WA, USA



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1), MN(1), ND(1), SD(1), WA(1)

**ID**

[ CBI Deleted ] -- Fremont County/Province, ID, USA, 10 acres.

**MN**

[ CBI Deleted ] -- Wilkin County/Province, MN, USA, 10 acres.

**ND**

[ CBI Deleted ] -- McHenry County/Province, ND, USA, 10 acres.

**SD**

[ CBI Deleted ] -- Marshall County/Province, SD, 10 acres.

**WA**

[ CBI Deleted ] -- Grant County/Province, WA, USA, 10 acres.



MONSANTO



*CBI-DELETED*

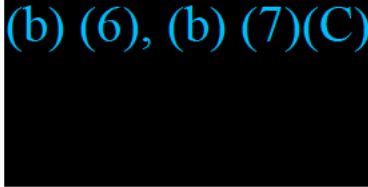
**Monsanto Reference ID**  
2003-250XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 20, 2003



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-250XRAB

Permit Unit

February 20, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-59n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-250XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 22, 2003 - March 22, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

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Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4 ;	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds Ship up to 10,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

ID, MN, MO, ND, SD, WA

#### **DESTINATION:**

ID, MN, MO, ND, SD, WA

#### **Ship From/Ship To:**

##### **ID**

[ CBI Deleted ] -- \*Fremont County/Province, ID, USA

##### **MN**

[ CBI Deleted ] -- \*Wilkin County/Province, MN, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **ND**

[ CBI Deleted ] -- \*McHenry County/Province, ND, USA

##### **SD**

[ CBI Deleted ] -- \*Marshall County/Province, SD

##### **WA**

[ CBI Deleted ] -- \*Grant County/Province, WA, USA



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-250XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**     ;

ID(1), MN(1), ND(1), SD(1), WA(1)

**ID**

[ CBI Deleted ] -- Fremont County/Province, ID, USA, 10 acres.

**MN**

[ CBI Deleted ] -- Wilkin County/Province, MN, USA, 10 acres.

**ND**

[ CBI Deleted ] -- McHenry County/Province, ND, USA, 10 acres.

**SD**

[ CBI Deleted ] -- Marshall County/Province, SD, 10 acres.

**WA**

[ CBI Deleted ] -- Grant County/Province, WA, USA, 10 acres.



MONSANTO



*CBI-DELETED*

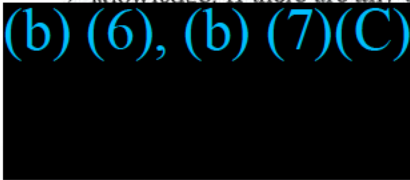
**Monsanto Reference ID**  
2003-250XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 20, 2003



file copy

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 25, 2003

Dear Mr. Cooper:


Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010538



file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 25, 2003

Dear Dr. Hanks:


Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010539



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010540



file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 25, 2003

Dear Mr. Nelson:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010541



file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

February 25, 2003

Dear Mr. Fridley:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010542



file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 25, 2003

Dear Mr. Wessels:


Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010543





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 25, 2003

RECEIVED

FEB 28 2003

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Cooper

Signature: (b) (6), (b) (7)(C)

Date: 2/28/03

State: Idaho

Rptloc01/R4



FEB 28 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 25, 2003

Dear Dr. Hanks:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination with the attached additional conditions

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature:

(b) (6), (b) (7)(C)

Date: 3-26-03

State: MN

Rptloc01/R4



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MAR 26 2003





## Minnesota Department of Agriculture

(651) 296-1277

March 26, 2003

Ms. Mary Jackson  
Biotechnology Program Operations - Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 03-052-59n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
  - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains) should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2003.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Nanks, Ph.D.  
State Biotechnologist





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverview, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 25, 2003

Dear Mr. Nelson:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-052-59n Applicant #: 2003-250XRAB  
Received: February 21, 2003 Effective: March 23, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: ID MN MO ND SD WA  
Release destination: ID MN ND SD WA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. *to Supplemental conditions letter March 18 2003*  
☐ State DOES NOT CONCUR and offers the following reasons:  
Name of State official: *David R. Nelson*  
Signature: (b) (6), (b) (7)(C)  
Date: *3/10/03*  
State: *ND* Rptloc01/R4



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MAR 12 2003



AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
Biotechnology Program Operations – Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale MD 27037

FROM: David R. Nelson

DATE: March 12, 2003

RE: Supplemental Conditions for Release of Wheat  
Bp 03-015-10n  
Bp 03-052-27n  
Bp 03-052-59n  
Bp 03-059-05n

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

#### North Dakota Supplemental Conditions 2003

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:

- Wheat, or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

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United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

February 25, 2003

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	03-052-59n	Applicant #:	2003-250XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MN MO ND SD WA		
Release destination:	ID MN ND SD WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/28/03

State: South Dakota

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 25, 2003

Dear Mr. Wessels:

Enclosed is notification 03-052-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-052-59n Applicant #: 2003-250XRAB  
Received: February 21, 2003 Effective: March 23, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: ID MN MO ND SD WA  
Release destination: ID MN ND SD WA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/3/03

State: WA

Rptloc01/R4



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MAR 3 2003



March 31, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 31, 2003.

Interstate movement and Release

Notification no. 03-052-59n (2003-250XRAB)

Regulated article - Wheat

Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.


This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination with the (attached) additional conditions.

In addition, the State of North Dakota concurs with APHIS determination with supplemental condition letter (attached) dated March 12, 2003.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

M. Cooper, Idaho Dept. of Agric., Boise, ID  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO

OR120018\_BR\_010551



• D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 03-052-59n



# Confirmation Report-Memory Send

Time : Apr-03-03 09:36am  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 232  
Date : Apr-03 09:33am  
To : 916367377085  
Document Pages : 04  
Start time : Apr-03 09:34am  
End time : Apr-03 09:36am  
Pages sent : 04  
Job number : 232

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-236

March 31, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 31, 2003.

Interstate movement and Release  
Notification no. 03-052-59n (2003-250XRAB)  
Regulated article - Wheat  
Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination with the (attached) additional conditions.

In addition, the State of North Dakota concurs with APHIS determination with supplemental condition letter (attached) dated March 12, 2003.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

M. Cooper, Idaho Dept. of Agric., Boise, ID  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



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(b) (6), (b) (7)(C), (b) (4)

CENTRAL REGION  
BIOTECHNOLOGY PERMIT  
FIELD RELEASE REPORT WORKSHEET

8/18/03

PERMIT NUMBER 03-052-594 CROP Wheat

ORGANIZATION / COMPANY Agroteck

RESPONSIBLE APPLICANT Mourah

COOPERATOR CONTACT PERSON (b) (6), (b) (7)(C), (b) (4)

LOCATION (b) (6), (b) (7)(C), (b) (4) North Dakota PHONE (b) (6), (b) (7)(C), (b) (4)

TYPE OF LOCATION: Farm Nursery Research ☒ General Other

DATE PPQ NOTIFIED OF FIELD RELEASE 6/2/03 ACTUAL DATE OF  
RELEASE April 21, 03

DATE OF FIELD INSPECTION 6/12/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS            CROP            PERMIT NUMBER
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☐ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH Potatoes and corn

SOUTH Farm yard

EAST Cultivated Field

WEST County Road

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH?           

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☐ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED 283 Acres  
NUMBER OF TRANSGENIC LINES IN TEST           

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS All used

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL?  
Cleaned in Plot Area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-3366  
LOCATION OF PPQ OFFICE           

OTHER PERSONS AT INSPECTION (b) (6), (b) (7)(C), (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST  
USDA, APHIS, PPQ PHONE: 573-893-6833

OR120018\_BR\_010554



(b) (6), (b) (7)(C), (b) (4)





Western Region  
Biotechnology Permit  
**Field Release Report Worksheet**  
For traditional and comprehensive permit inspections

Permit Number: 03-052-594 Crop: WHEAT  
Organization/Company: MONSANTO  
Responsible Applicant: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C), (b) (4)  
Cooperator Contact Person: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)  
Location of site: (b) (6), (b) (7)(C), (b) (4) ID  
Type of location: Farm ☐ Nursery ☐ Other ☒ (describe) RESEARCH PLOT  
Date of PPQ notified of field release: \_\_\_\_\_ Actual date of release: 03-31-03

1. Cooperator had copy of permit and conditions? Y ☒ N ☐
2. Were volunteer plants found from a previous field release? NO PREVIOUS RELEASE Y ☐ N ☒  
If yes, Number of volunteers \_\_\_\_\_, crop \_\_\_\_\_, permit number \_\_\_\_\_
3. Was plot specific location according to permit? Y ☒ N ☐
4. Was security according to permit protocol? Y ☒ N ☐
5. Was plot dimensions according to permit? Y ☒ N ☐
6. What was on each side of test plot?  
North BARLEY  
East "  
South "  
West "
7. Border buffer area required? Y ☒ N ☐  
If yes, How much? 10 FEET
8. Were special permit conditions met? Y ☒ N ☐
9. Was the seed storage area inspected? Y ☒ N ☐
10. Were shipping containers inspected? Y ☐ N ☒
11. Number if regulated articles released ONE  
Number of transgenic lines in test (phenotypes wanted) ONE
12. Describe disposal of any extra seeds or plants DEVITALIZED BY BURNING
13. Was equipment cleaned of seed and plant material? Y ☒ N ☐  
If no, explain in cover memo

Revised 7/7/03

OR120018\_BR\_010556



14. Were any violations or discrepancies found?

Y ☐

N ☒

(b) (6), (b) (7)(C)

Inspecting Officer Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

LOUIS H. DERSCHE

Phone: 208-733-5719 208-724-2397

Location of PPQ Officer: TWIN FALLS ID

Names and Affiliation of Any Other Persons at the inspection:

(b) (6), (b) (7)(C), (b) (4)

(Report due 10 days after field release)

Please fax or email completed worksheet to:

Ralph Stoaks, Regional Biotechnologist

2150 Centre Ave. Bldg. B, 3E10

Ft. Collins, CO 80526

Phone: 970-494-7573

Fax: 970-494-7576

Email: ralph.d.stoaks@aphis.usda.gov

Please FedEx original worksheet to:

Tony Roman, Chief Biotechnology Program Operations

4700 River Road, Unit 147, 5B53

Riverdale, MD 20737

Phone: 301-734-0029

Revised 7/7/03

OR120018\_BR\_010557



(b) (6), (b) (7)(C), (b) (4)





**COMPLIANCE FORMS**

This section of the compliance packet contains the three forms that must be completed and returned to Monsanto. The information you provide enables us to assure the trial is being conducted according to agency requirements, and to make accurate and timely reports to the federal agencies on the conduct of this field trial.

**PLEASE BE SURE TO FILL IN ALL BLANKS ON THESE FORMS. ALL INFORMATION MUST BE PROVIDED.**

<b>COMPLETE AND RETURN THE FOLLOWING THREE FORMS:</b>		
	<b><u>NAME OF FORM</u></b>	<b><u>WHEN IS IT DUE?</u></b>
#1	<b>Planting Information and Certification of Field Trial Compliance</b>	<b>Two weeks after planting or immediately after "no plant" decision</b>
#2	<b>In-Season Field Monitoring</b>	<b>Two weeks after harvest or destruction of the trial</b>
#3	<b>Monitoring for Volunteers</b>	<b>After completion of volunteer monitoring period</b>

Two additional forms in the packet:

**Unintentional Release Form** -- Complete and return to us in the event of an unintentional release.

**Agency Visit Form** -- Complete and return to us if you receive an agency visit.



## PLANTING INFORMATION AND CERTIFICATION OF FIELD TRIAL COMPLIANCE

Planting Information and Certification of Field Trial Compliance USDA #: 03-052-59n Monsanto #: 2003-250XRAB

It is necessary that you strictly adhere to all federal, state and local regulations as described in your compliance packet.

Please fill in all information requested. Sign, date and fax to 636/737-7085 within 2 weeks of planting. Or you can mail a completed copy of the questionnaire to the address shown at the bottom of the page. Retain the original of this completed form with your compliance packet.

**IF ANY OF THE PREFILLED INFORMATION BELOW IS INCORRECT, YOU MUST CONTACT THE COMPLIANCE SPECIALIST PRIOR TO PLANTING.** Contact Priscilla E. Hunter at 636/737-6032 with corrections or questions.

Monsanto #: 2003-250XRAB USDA #: 03-052-59n Crop: Wheat

Applicable EPA Regulation: N/A

Responsible Release Site Person/Researcher:

Name: (b) (6), (b) (7)(C), (b) (4)

Address:

(b) (6), (b) (7)(C), (b) (4) ID (b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4) FAX: (b) (6), (b) (7)(C), (b) (4)

E-MAIL: (b) (6), (b) (7)(C), (b) (4)

FARM/COMPANY NAME	FARM/COMPANY ADDRESS	RELEASE COUNTY	RELEASE STATE
(b) (4)	(b) (4)	Fremont	ID
	(b) (4) ID		
PROTOCOL CODE			

WAS THIS SITE PLANTED? ☒ Yes ☐ No (circle one and answer questions below, if planted.)

PLANTING DATE: 5/15/02 <sup>with 5/16/02</sup> Project/Trial Identifier: 03-01-66-09

GPS COORDINATES: Latitude (b) (4); Longitude (b) (4)

ACREAGE PLANTED: Regulated Acreage\* 0.05; USDA Acreage\*\* 0.75

\*Acreage planted of regulated material only; \*\*Total acreage planted, including border rows.

WHAT ISOLATION METHOD HAVE YOU USED TO ASSURE CONTAINMENT OF THE REGULATED MATERIAL IN THE FIELD? (Refer to the "Persistence in the Environment" section of the Crop Performance Standards for options acceptable to the USDA and to the EUP approval letter, if applicable.)

330ft Isolation Distance.  
Barley as crop in surrounding field.

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

Priscilla E. Hunter - Phone: 636/737-6032 eMail: priscilla.e.hunter@monsanto.com Fax: 636/737-7085  
Monsanto Company - 700 Chesterfield Parkway West - Chesterfield, MO, 63017

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Planting Information and Certification of Field Trial Compliance USDA #: 03-052-59n Monsanto #: 2003-250XRAB

**Certification Questions:**

1. Have you read the material for this packet which is relevant to your field activities?  
Yes ☒ No ☐
2. Have you received biotech field compliance training from Monsanto? Yes ☒ No ☐  
If answered yes, (b) (6), (b) (7)(C), (b) (4)  
Who trained you? \_\_\_\_\_  
When were you trained? 4/7/03
3. Is this test material also governed by regulations under an EUP? (refer to the approvals section of this packet) Yes ☐ No ☒
4. Are there any additional requirements for this USDA Notification which are applicable to the field trial? (Refer to the USDA approval letter in the approvals sections of this packet.)  
Yes ☐ No ☒

To the best of my knowledge, all of the answers are true and correct and no information has been omitted.

(b) (6), (b) (7)(C), (b) (4)

Signature of Site Responsible Researcher

5/15/03

Date

(b) (6), (b) (7)(C), (b) (4)

Printed Name

(b) (6), (b) (7)(C), (b) (4)

E-Mail Address

Other Comments/Information: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_WSR  
5/15/03

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

Priscilla E. Hunter - Phone: 636/737-6032 eMail: priscilla.e.hunter@monsanto.com Fax: 636/737-7085  
Monsanto Company - 700 Chesterfield Parkway West - Chesterfield, MO, 63017

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## IN-SEASON FIELD MONITORING

Complete one form per site and RETURN THIS FORM WITHIN 2 WEEKS AFTER HARVEST OR CROP DESTRUCTION to your Compliance Specialist (name and address at the bottom of this page). If you replant a site (e.g. in a continuous nursery), then you must submit an "In-Season Field Monitoring" form for each planting. If your crop is alfalfa, you may wish to make extra copies of this form for the additional In-Season Field Monitoring that is required.

USDA #:	03-052-59n	Monsanto #:	2003-250XRAB
Crop:	Wheat	Project/Trial Identifier:	03-01-66-09
GPS Coordinators (specify Lat/Long):	(b) (4)		

## Site Information

Farm/Company Name:

(b) (4)

(b) (4) ID (b) (4)

Release Site Location (including county/state): Fremont/ID

Responsible Release Site Person/Researcher &amp; Phone No./FAX:

(b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4) FAX: (b) (6), (b) (7)(C), (b) (4)

E-MAIL: (b) (6), (b) (7)(C), (b) (4)

FILL IN ALL BLANKS. (Additional space is available on last page of form.)

Purpose of Field Test	Efficacy Comparison		
Number of Seeds Received per Event	Number: 5165	From: Monsanto	Date: 4/14/03
Line Numbers/Events Planted	1) 33391		
Number of Seeds Planted per Event	5165		
Planting Date	5/15/03		
Actual Acres Planted of the regulated test event(s) (excluding border rows)	0.05		
Disposition of leftover Seeds after Planting	Buried in Plot AREA 12" Deep.		
Disposition of Seed Containers after Planting (e.g. bags, envelope, etc.)	IN GMO Storage		
Harvest Date (if applicable)	8/15/03		
Disposition of Seeds (after harvest) -if cotton, include gin trash	All seed sent to Monsanto		
Crop Destruct (for trial/plot)	Method:	Date:	
Was the trial destroyed prior to pollen flow or seed set?	YES	(NO)	(Circle one)

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

(b) (6), (b) (7)(C)

Fax: 636/737-7085

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Monsanto Company - 700 Chesterfield Parkway West - Chesterfield, MO, 63017

OR120018\_BR\_010562



Continuation of In-Season Field Monitoring USDA #: 03-052-59n Monsanto #: 2003-250XRAB

**Instructions for Recording Observations:**

Following are guidelines for consideration while making observations at least once every 4 weeks during the growing season. This list is in no way inclusive of what may be observed. If multiple lines are planted under the same notification, please identify the specific lines affected. If no control is available in the plot, compare to other plants within the growing area or compare how the plant is growing in relation to standard hybrids/lines in that area. If something unusual is noted during the field trial that is not covered by the categories listed, please record the observation on the reverse side of the form or attach additional sheets as necessary.

Use a new line for each observation date recorded. Attach additional sheets if more room is needed to record observations.

Disease Susceptibility of the Regulated Plant - Do regulated plants have a higher incidence of disease than non-regulated plants? What diseases are observed?

(b) (4)

**RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:**

Priscilla E. Hunter - Phone: 636/737-6032 eMail: priscilla.e.hunter@monsanto.com Fax: 636/737-7085  
Monsanto Company - 700 Chesterfield Parkway West - Chesterfield, MO, 63017

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Continuation of In-Season Field Monitoring USDA #: 03-052-59n Monsanto #: 2003-250XRAB

**Plant Growth (Shape and Form) Characteristics** - Is there a difference in the general appearance, growth or flowering characteristics and/or seed production between the regulated and non-regulated plants? Describe the differences. Is there a difference in the emergence pattern (accelerated or delayed) or emergence duration (time from initial emergence to time when all plants are emerged) between the regulated and non-regulated plants? Describe differences and potential causes.

(b) (4)

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

Priscilla E. Hunter - Phone: 636/737-6032 eMail: priscilla.e.hunter@monsanto.com Fax: 636/737-7085  
Monsanto Company - 700 Chesterfield Parkway West - Chesterfield, MO, 63017

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*CONFIDENTIAL***COMPLIANCE SITE DETAIL LISTING**

USDA #: 03-052-59a

Monsanto #: 2003-250XRAB

Farm/Company: [CBI-DELETED]County of Release: [CBI-DELETED]Maximum USDA Approved Acres: [CBI-DELETED]PROTOCOL CODES:EUP ACRES

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SDFarm/Company: [CBI-DELETED]County of Release: [CBI-DELETED]Maximum USDA Approved Acres: [CBI-DELETED]PROTOCOL CODES:EUP ACRES

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WAFarm/Company: [CBI-DELETED]County of Release: [CBI-DELETED]Maximum USDA Approved Acres: [CBI-DELETED]PROTOCOL CODES:EUP ACRES

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(b) (4)



(b) (4)

OR120018\_BR\_010567

MAINFAX

08/03/2003 17:33 FAX 8086610344

USDA

United States  
Department of

Animal and  
Plant Health

Biotechnology

1-001

1-01/04

1-001

1-007

1-01/04

1-001



## WHEAT FIELD RELEASE PERFORMANCE STANDARDS

Notification to allow movement of material regulated by the USDA-APHIS must be in place prior to shipment. This includes shipment of the seed (or other plant material) to a site to initiate a field trial as well as shipment of harvested seed (or other plant material) from a field trial site to another location. Harvested commodities from field trials of regulated plant material must not be allowed to enter commerce as a food or feed product.

### Shipping

When shipping, all packages must be clearly labeled as to content and the USDA notification number must be prominently displayed on the outer package (for example, USDA #00-000-00a, Wheat).

Regulated plant materials shipped will include any viable plant parts as described in the notification. For most plant material, any shipping container that consists of an inner container that is a sturdy bag, box, or other such structure, enclosed in an outer container that is also a sturdy bag, box, or other such structure is acceptable under most circumstances. Both inner container and outer container must be capable of preventing seed or material loss.

If transfer of the regulated material is to take place within the state and is not noted on the notification, the state regulatory official must be contacted before the movement may occur. The name and the phone number of the state official to contact can be found in the letter immediately after the cover page in the compliance packet.

### Maintenance at Destination

When regulated material is received at contained facilities, such as storage rooms or greenhouses, it should be handled and stored in such a way that there is no release into the environment (for example, stored in a locked file or storage cabinet). This requires ensuring that regulated material is not accidentally mixed with non-regulated material, does not transfer genes to non-regulated material inside or outside the facility, and does not accidentally escape from the contained facility.

To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as obvious marks, color-coding, or strict segregation of material should be implemented.

Seed and/or other plant material that will be planted directly in the field should be kept secure until needed for planting. If excess seed and/or plant material exists after planting, this material should be devitalized using suitable means as given in the "Devitalization" section of this document or returned to the contained facility. To minimize pollen-mediated gene flow out of a contained facility, physical barriers or methods such as sterilization or bagging should be used. Similar methods should be used to prevent pollen flow to receptive plants within the contained facility as well.

### Persistence in the Environment

To prevent the regulated material in the field trial from persisting in the environment, devitalization treatments given in the "Devitalization" section of this document, should be utilized. To prevent offspring from being formed and persisting, means must be taken to minimize the likelihood of pollination and successful fertilization of receptive plants outside the field trial area.

The following are minimum standards of isolation that will minimize the likelihood of pollination of receptive wheat, durum or triticale plants outside of the field trial area:

- 1) A minimum isolation distance of 33 feet (10 M) must be maintained between the trial and any wheat, durum or triticale planting that will produce seed to be saved for seed production.

The isolation area from the trial can be:



**Wheat Performance Standards (Cont'd)**

- \* Fallow or bare ground
- \* Crops other than small grains
- \* Physical isolation such as road ditches, farmsteads, fence rows, wind breaks, etc.

OR

**2) Destruction of the wheat trial prior to flowering.**

When the field trial is located on a privately-owned farm, the responsible researcher must inform the owner of the farm as to the nature of the experiment and the need to maintain these plants and seed separately from any other plant material that is not part of the trial. The cooperator and/or owner should be instructed as to the need to frequently observe the plots for any signs of crop damage or vandalism and immediately report any such acts to Monsanto.

**Inadvertent Mixing of Materials in Environmental Releases**

Inadvertent mixing of regulated material and non-regulated wheat should be avoided. Inadvertent mixing may be prevented by planting each regulated article in a defined area with an unplanted alley between it and any other material. The width of this alley will vary depending on the method of harvesting and other operations. For machine harvesting, the alley should be wide enough to allow for machine movement without mechanical mixing. **All machinery (planting, maintenance, and harvesting) that may retain viable plant material should be cleaned after use in the regulated field, and before moving the equipment out of the regulated field. This will ensure that any regulated material retained by machinery will remain in the regulated field.**

For all plantings, identity must be maintained by planting regulated plants in distinct plots. Clearly stake out the plot, including border rows with easily identifiable markers (for example, metal or wooden stakes). It should remain clearly identified for the duration of the volunteer monitoring period. The use of stakes or markers to define the area where the regulated plants are grown will help in identifying volunteers for later elimination.

**Devitalization**

In a contained facility, seed and other material capable of natural propagation should be devitalized before leaving the contained facilities and/or placed in suitable containers prior to being shipped to another facility (see "Shipping") to prevent accidental release in the environment. Suitable means of devitalization at contained facilities include the use of:

- \* dry or steam heat
- \* physical grinding
- \* chemicals or
- \* composting (at a location that can be monitored until devitalization occurs).

In an environmental release, plant material or seed may also be disposed of according to the conditions of your field project plan/protocol. For example, send seed back to the origination point, or to post-harvest location(s) in appropriate containers, bury or disk in the field plot, etc. Final disposition and devitalization, after harvest, may also be achieved by one of the following methods: hand weeding, grinding, incineration, chemical application or mechanical cultivation. In some cases, the remaining vegetative material in the field can be incorporated into the soil and left to natural devitalization by the elements. These requirements apply to the entire plot area, including the border rows.



**Wheat Performance Standards (Cont'd)****Post-Harvest Monitoring for Volunteer Plants**

The area (plot area including border rows) must be monitored for volunteers and all volunteers must be destroyed. Volunteers can be minimized by growing regulated material in defined areas in the field and by utilizing adequate termination protocols. Wheat trials destroyed before flowering still require volunteer monitoring due to seed dormancy.

After field trial completion, plots will be monitored for a period of twenty-four (24) months. If volunteers are still present at the last monitoring time, continue to monitor for volunteers and contact your compliance specialist.

Volunteers will be removed prior to seed set or flowering. Methods that can be used to eliminate volunteers include tillage, herbicide application, and hand weeding.

Arrangements must be made to allow access to the land for the volunteer-monitoring period.

Replanting of the field trial plot during the next field season must be done in such a manner as to allow for appropriate volunteer monitoring. Options for replanting the test and border row areas are:

- \* Leave the site fallow and control any volunteer plants.
- \* Plant to another appropriate rotational crop which would allow the clear identification and control of volunteer wheat plants.
- \* Plant to regulated wheat and follow the requirements for that regulated wheat material.
- \* If planting to a non-regulated crop of the same species, the rules for field testing a regulated field trial must be followed.

The following requirements must be met in continuous nursery situations, as in Hawaii and Puerto Rico:

- \* The field should remain fallow for a minimum of 30 days or an additional time period mandated by the State Department of Agriculture. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Then the volunteer wheat should be destroyed. Any additional requirements mandated by the State Department of Agriculture must be met.

**Compliance**

The site responsible researcher must:

- 1) Comply with all applicable requirements set forth in this Crop Performance Standard.
- 2) Have the Crop Performance Standard available during a USDA inspection.
- 3) Notify the Monsanto compliance specialist within 24 hours of any compliance violation or unintentional release of regulated material.

If a compliance violation or unintentional release occurs, stabilize the situation first, then gather information and call the compliance specialist. The proper agency authorities will then be contacted by the Monsanto Compliance Team, as required.

Examples of compliance violations:

- \* Allowing regulated material to enter commerce
- \* Failure to adhere to isolation requirements, as described in Crop Performance Standard
- \* Failure to have the Crop Performance Standard available during a USDA inspection



**Wheat Performance Standards (Cont'd)**

- \* Feeding of regulated plant material to livestock
- \* Failure to monitor for volunteers
- \* Planting without an approved notification
- \* Conducting trial activities outside of the approved dates of the notification
- \* Moving planting or harvesting equipment from the plot site before cleaning
- \* Mixing regulated plant material with non-regulated plant material
- \* Planting at an unapproved site or in an unapproved state
- \* Planting more acreage than approved on the notification
- \* Shipping to an unapproved location or to an unapproved state
- \* Loss of seed by shipping company, applicant or designated representative
- \* Movement of seed or regulated plant material outside the test area by natural causes (floods, tornadoes, etc.)





United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Plant Protection  
and Quarantine

7150 Humphrey Drive  
Suite 2189  
Minneapolis MN 55450

Phone: (612) 725-1771  
Fax: (612) 725-1741

July 31, 2003

W. Scott Wood  
USDA, APHIS, PPQ  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606

Mr. Wood,

On July 29, 2003 I inspected field release notification site 03-052-59n. (b) (6), (b) (7)(C) accompanied me.

As the attached questionnaire indicates, all field test site requirements were met. (b) (6), (b) (7)(C) had retained photocopies of the shipping labels; this was very helpful in determining that the material had retained its identity.

(b) (6), (b) (7)(C) and I discussed the MDA condition that no wheat be grown within the trial plot or within an area extending 33 ft. from the outside of the trial plot for two growing seasons.

Please let me know if you would like any further information,

Thank you,

Scott Smith



APHIS Protecting American Agriculture

Equal Opportunity Employer

OR120018\_BR\_010572



APHIS Notification Number(s): 03-052-59n Crop: Wheat  
Applicant's Name: Monsanto Trait/Gene: HT  
Name of Cooperator at Inspected Site: (b) (4), (b) (6), (b) (7)(C) Phone: (b) (4), (b) (6), (b) (7)(C)  
Location of Site: (b) (4), (b) (6), (b) (7)(C) MN Date of Inspection: 7/29/03  
Type of Location: Farm X Nursery      Research      Other      (Describe)       
GPS Coordinates (If available): Latitude (b) (4), (b) (6), (b) (7)(C) Longitude (b) (4), (b) (6), (b) (7)(C)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

### I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Y  
B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Y

### II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Yes
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants? Yes
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- |   |     |   |
|---|-----|---|
| <u>    </u> 1. Removing flowers.  |     |   |
| C.1. Is there any evidence that the plants have flowers or that flowers have been removed?  | Y   | N |
| <u>    </u> 2. Bagging flowers/tassels  |     |   |
| C.2. Does the applicant have material to bag reproductive structures?   | Y   | N |
| <u>    </u> 3. Terminating the experiment before flowering.   |     |   |
| C. 3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen?  | Y   | N |
| <u>  X  </u> 4. Physical isolation.   |     |   |
| C. 4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? | Yes |   |
| <u>    </u> 5. Temporal isolation.  |     |   |
| C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap?  | Y   | N |
- D. If the applicant's design standards use border rows, are there the state number of border rows? NA



- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Yes
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? NA
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Yes, will disk any germinated volunteer under.
- H. Was the field site marked as stated in the design standards? Small flags at corners and inside plot
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Yes
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? See G above

**III. Devitalization.**

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Buried and disked under as it germinates
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: Scott Smith

Phone: 612 725 1771

Location of PPQ Office: Minneapolis

Names and Affiliation of Any Other Persons at the Inspection:

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Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region



WESTERN REGION  
BIOTECHNOLOGY PERMIT  
HARVEST REPORT WORKSHEET

8/20/03

PERMIT NUMBER 03-052-59n CROP R.R. Wheat

ORGANIZATION /COMPANY Monsanto

LOCATION (b) (4) WA (b) (4)

DATE OF PPQ NOTIFIED OF HARVEST 8/4/03 ACTUAL HARVEST DATE 8/6/03

DATE OF HARVEST INSPECTION 8/11/03

HOW WAS CROP TERMINATED? Combine Harvested and plowed under

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Combined and threshed out. All stubble and plant debris has been plowed under.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor used to clean ~~the~~ combine and all equipment associated with harvest of

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? yes WHERE? (b) (4) regulated material no.

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? Monitor two years for volunteers

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

(b) (6), (b) (7)(C)

INSPECTING PPQ OFFICER George Bruno PHONE (509) 353-2950  
LOCATION OF PPQ OFFICE Spokane WA

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager  
USDA, APHIS, PPQ  
9580 Micron Avenue, Suite I  
Sacramento, CA 95827  
Phone: (916) 857-6105  
FAX: (916) 857-6100

REVISED 01/24/97

OR120018\_BR\_010575



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-052-59n** **Monsanto #2003-250XRAB**

**April 7, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317663	Fremont	ID
2147317661	Wilkin	MN
7408	McHenry	ND
8043	Marshall	SD
519	Grant	WA

**Fremont County/ID (2147317663)**

(b) (4)

4/8/04  
epd



(b) (4)

Wilkin County/MN (2147317661)

(b) (4)



(b) (4)

McHenry County/ND (7408)

(b) (4)



(b) (4)

Marshall County/SD (8043)

(b) (4)



(b) (4)

Grant County/WA (519)

(b) (4)



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



**CBI-DELETED**

**2003 Wheat Field Test Report**  
**USDA #03-052-59n**                      **Monsanto #2003-250XRAB**

**April 7, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317663	Fremont	ID
2147317661	Wilkin	MN
7408	McHenry	ND
8043	Marshall	SD
519	Grant	WA

**Fremont County/ID (2147317663)**

**Planting Date:** 05/15/2003

**Harvest Date:** 08/15/2003

**Destruct Date:** 09/04/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



**Wilkin County/MN (2147317661)**

**Planting Date:** 04/26/2003

**Harvest Date:** 08/14/2003

**Destruct Date:** 08/15/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**McHenry County/ND (7408)**

**Planting Date:** 04/21/2003

**Harvest Date:** 08/12/2003

**Destruct Date:** 08/13/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]



**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Marshall County/SD (8043)**

**Planting Date:** 04/25/2003

**Harvest Date:** 08/11/2003

**Destruct Date:** 08/21/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Grant County/WA (519)**

**Planting Date:** 04/22/2003

**Harvest Date:** 08/06/2003

**Destruct Date:** 08/07/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]



• **Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]



Sept. 8, 2003

Tony Roman, Ralph Stoaks

Tony and Ralph,

This inspection was very late, and all that remained of the trial was stubble. For weeks I tried to contact (b) (4), (b) (6), (b) (7)(C) at the phone number listed. When the line was not busy, there was no answer. On 08-22-03 I sent a letter asking (b) (4), (b) (6), (b) (7)(C) to call me ASAP. He phoned from Hawaii on 09-02-03 to set up an appointment for the inspection.

The inspection consisted of a tour of the growing area (shown on the site map), inspection of the storage area, the plot planter, and the plot combine. (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) was present to answer questions.

The seed ( five pounds total) arrived direct from Monsanto via FedEx 04-14-03. The seed was triple packed in manilla envelopes in ziplock bags in a cardboard box. The seed was locked in a signed storage cabinet until planting. The seed was planted 05-15-03 using a small plot planter. The planter was then vacuumed in the plot area, and the material collected was immediately buried approx. 12 inches deep.

The wheat grew normally and was chemically treated and monitored according to Monsanto protocols.

The crop was harvested 08-15-03 with a small plot combine dedicated to research. The combine was then swept out and washed in the growing area. All leftover plant material was buried 12 inches deep in the plot. All harvested seed was packaged immediately and immediately shipped back to Monsanto in St. Louis MO by FedEx overnight.

The test plot area will be left fallow or planted with potatoes in 2004, and monitored for wheat volunteers.

(b) (6), (b) (7)(C)

Louis Dersch  
PPQ Officer



3/03/03 12:23 pm

## Notification Tracking Sheet

=====

Bp number: 03-058-02n

=====

App number: 2003-256XRAB  
 Received: 2/27/03  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 3/29/03  
 Phenotype: HT - Glyphosate tolerant  
 Comments:

Begin movement: 3/26/03  
 End movement: 3/26/04  
 Begin release: 3/26/03  
 End release: 3/26/04  
 Acre: 30.00  
 CBI status: CBI

Resp person: **(b) (6), (b) (7)(C)**  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: **(b) (6), (b) (7)(C)**

Fax: 636-737-7085

- |  | Initial  | Date        |
|--|----------|-------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ aid ]  | [ 3/4/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ AMK ]* | [ 3/4/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed ex</i> | [ K&O ]  | [ 3/5/03 ]* |
| 4. <input type="checkbox"/> State response   |          |             |

O/d	Loc	Site	Reg
Interstate	*Dest*CA	*	*WR *
Interstate	*Dest*MN	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Orig*CA	*	*WR *
Interstate	*Orig*MN	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*SD	*	*SCR *
Release	* *MN	*	1*NER *

- |  |         |             |
|--|---------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ aid ] | [ 3/4/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ K&O ] | [ 4/1/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ K&O ] | [ 4/3/03 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify |         |             |

OR120018\_BR\_010589

6



*CONFIDENTIAL***MONSANTO COMPANY**700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>**Monsanto Reference ID**  
2003-256XRAB

Permit Unit

February 24, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-058-02n

**1. USDA Reference Number****2. Application Reference Number** 2003-256XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Monsanto Company

Email

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 26, 2003 - March 26, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-256XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



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Monsanto Reference ID  
2003-256XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

200,000 Ship up to 200,000 pounds wheat seed to and from each location.

### ORIGIN:

CA, MN, MO, SD

### DESTINATION:

CA, MN, MO, SD

### Ship From/Ship To:

CA

(b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MN

\* (b) (4) Marshall County/Province, MN (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

\* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA

] -CBI

SD



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**Monsanto Reference ID**  
2003-256XRAB

\* [REDACTED] (b) (4) Brookings  
County/Province, SD, (b) (4) USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) SD, [REDACTED] USA (b) (4), (b) (6), (b) (7)(C)

J-CBI



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**Monsanto Reference ID**  
2003-256XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN(1)

MN

(b) (4), (b) (6), (b) (7)(C) Marshall County/Province, MN, (b) (4), (b) (6), (b) (7)(C) USA, 30 acres.

**RESPONSIBLE PERSON/RESEARCHER:**

(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

J-CBI



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*CONFIDENTIAL*

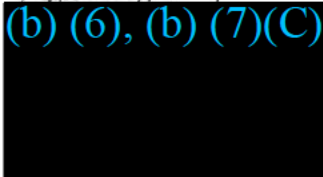
**Monsanto Reference ID**  
2003-256XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 24, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

February 24, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-058-02n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-256XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 26, 2003 - March 26, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

200,000 Ship up to 200,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

CA, MN, MO, SD

#### **DESTINATION:**

CA, MN, MO, SD

#### **Ship From/Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**MN**

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN(1)

MN

[ CBI Deleted ] -- Marshall County/Province, MN, USA, 30 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2003



MONSANTO



*CBI-DELETED*

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2003-256XRAB

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Permit Unit

February 24, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-058-02n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-256XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 26, 2003 - March 26, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	; NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

200,000 Ship up to 200,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

CA, MN, MO, SD

#### **DESTINATION:**

CA, MN, MO, SD

#### **Ship From/Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**MN**

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-256XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:** *i*

MN(1)

MN

[ CBI Deleted ] -- Marshall County/Province, MN, USA, 30 acres.



MONSANTO



*CBI-DELETED*

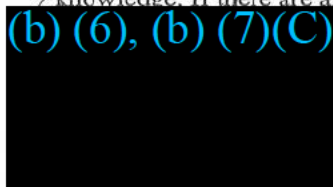
**Monsanto Reference ID**  
2003-256XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 24, 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 3, 2003

Dear Mr. Brown:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-058-02n	Applicant #:	2003-256XRAB
Received:	February 27, 2003	Effective:	March 29, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MN MO SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010609



file copy

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 3, 2003

Dear Mr. Brown:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-058-02n	Applicant #:	2003-256XRAB
Received:	February 27, 2003	Effective:	March 29, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MN MO SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010610



file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

March 3, 2003

Dear Dr. Hanks:


Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-058-02n Applicant #: 2003-256XRAB  
Received: February 27, 2003 Effective: March 29, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CA MN MO SD  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010611



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 3, 2003

Dear Mr. Brown:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-058-02n	Applicant #:	2003-256XRAB
Received:	February 27, 2003	Effective:	March 29, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MN MO SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010612



file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 3, 2003

Dear Mr. Fridley:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-058-02n	Applicant #:	2003-256XRAB
Received:	February 27, 2003	Effective:	March 29, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MN MO SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010613





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 3, 2003

Dear Mr. Brown:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-058-02n      Applicant #: 2003-256XRAB  
Received: February 27, 2003      Effective: March 29, 2003  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: CA MN MO SD  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPO, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).  
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: March 10, 2003

State: California

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

March 3, 2003

Dear Dr. Hanks:

Enclosed is notification 03-058-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-058-02n Applicant #: 2003-256XRAB  
Received: February 27, 2003 Effective: March 29, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CA MN MO SD  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination *with the attached additional conditions*

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-26-03

State: MN

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 3, 2003



Dear Mr. Fridley:

Enclosed is notification 03-058-02n for your information. This information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-058-02n	Applicant #:	2003-256XRAB
Received:	February 27, 2003	Effective:	March 29, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MN MO SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Speaks, FPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Kevin Fridley

Signature:

(b) (6), (b) (7)(C)

Date:

3/6/03

State:

South Dakota

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

MAR 6 2003

OR120018\_BR\_010616



April 1, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 1, 2003.

Interstate movement and Release

Notification no. 03-058-02n (2003-256XRAB)

Regulated article - Wheat

Destinations - California, Minnesota, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

In addition, the State of Minnesota concurs with APHIS determination with (attached) additional conditions.

copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

181  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
File number 03-058-02n

OR120018\_BR\_010617



California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 03-058-02N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota and Missouri shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.





## Minnesota Department of Agriculture

(651) 296-1277

March 26, 2003

Ms. Mary Jackson  
Biotechnology Program Operations - Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 03-058-02n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
  - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains) should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2003.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.  
State Biotechnologist



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-058-02n** **Monsanto #2003-256XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

**Location**  
2147318043

**County**  
Marshall

**State**  
MN

**Marshall County/MN (2147318043)**

(b) (4)

aid  
2/18/04



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-058-02n                      Monsanto #2003-256XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147318043	Marshall	MN

**Marshall County/MN (2147318043)**

**Planting Date:** 05/27/2003

**Harvest Date:** 09/06/2003

**Destruct Date:** 09/06/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]





United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Plant Protection  
and Quarantine

7150 Humphrey Drive  
Suite 2189  
Minneapolis MN 55450

Phone: (612) 725-1771  
Fax: (612) 725-1741

July 31, 2003

W. Scott Wood  
USDA, APHIS, PPQ  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606

Mr. Wood,

On July 29, 2003 I inspected field release notification site 03-058-02n. Glenn Rivard accompanied me.

As the attached questionnaire indicates, all inspection requirements were met. The plot is surrounded by a 5' fallow border which is then within a bean field.

Please let me know if you would like any further information,

Thank you,

(b) (6), (b) (7)(C)

Scott Smith

CS  
8/20/03



APHIS Protecting American Agriculture

Equal Opportunity Employer

OR120018\_BR\_010625



APHIS Notification Number(s): 03-058-02n

Crop: Wheat

Applicant's Name: Monsanto

Trait/Gene: HT

Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4)

Location of Site: (b) (6), (b) (7)(C), (b) (4) MN

Date of Inspection: 7/29/03

Type of Location: Farm ☒ Nursery ☐ Research ☐ Other ☐ (Describe) ☐

GPS Coordinates (If available): Latitude (b) (6), (b) (7)(C), (b) (4) Longitude (b) (6), (b) (7)(C), (b) (4)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

**I. Shipping, Maintenance at Destination, and Identification**

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Yes
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Yes

**II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants**

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? 103 ft to the east is closest wheat Yes
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located inside the pollination distance for the plants? Fallow area around plants kept clean; beans sprayed for weeds
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- \_\_\_\_ 1. Removing flowers.  
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N
- \_\_\_\_ 2. Bagging flowers/tassels  
C.2. Does the applicant have material to bag reproductive structures? Y N
- \_\_\_\_ 3. Terminating the experiment before flowering.  
C. 3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N
- X  4. Physical isolation.  
C. 4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? Yes
- \_\_\_\_ 5. Temporal isolation.  
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N

- D. If the applicant's design standards use border rows, are there the state number of border rows? NA



- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Individual plots within trial separated by alleys
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards?  
NA
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards?  
Yes
- H. Was the field site marked as stated in the design standards? Yes, large metal stakes at corners
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts?  
Yes
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive?  
Yes

**III. Devitalization.**

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)?  
Yes
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: Scott Smith Phone: 612 725 1771

Location of PPQ Office Minneapolis

Names and Affiliation of Any Other Persons at the Inspection:

---



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Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.





## CONFIDENTIAL BUSINESS INFORMATION

MONSANTO COMPANY

800 NORTH LINDBERGH BOULEVARD

ST. LOUIS, MISSOURI 63167

PHONE (314) 694-1000

<http://www.monsanto.com>

August 30, 2005

Mr. Gregg Goodman  
Regulatory Specialist, Compliance  
Permitting and Notification  
USDA, APHIS, BRS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Re: USDA#03-058-02n      Monsanto #2003-256XRAB

Dear Mr. Goodman:

Monsanto is reporting a volunteer-monitoring situation in which a few regulated wheat volunteers were not destroyed before viable seed was produced.

A regulated wheat trial was planted in Marshall County, MN on 5/5/03 and destroyed on 9/6/03. The total regulated acreage planted was 9.45 acres. The plot has been monitored for wheat volunteers since destruction of the trial.

Volunteer wheat plants in the 2-leaf stage were observed on 6/6/05 at a density of approximately 1/100 sq. ft. The herbicide application to kill the volunteers could not be made until 7/6/05 because the field was too wet from excessive rainfall. (The field had received 12 inches of rainfall between 5/5/05 and 7/6/05.) Even on the date of application, the normal application equipment could not be used because the field was still too wet. Instead, a 4 wheel ATV equipped with a small tank and spray boom was used. A second herbicide application was made on 8/2/05.

On 8/25/05, the researcher informed Monsanto that he had discovered that 5 plants along the edge of the trial in a confined area within the trial border had produced viable seed. All the other volunteers in the plot area had been rendered sterile by the herbicide spray. The 5 plants that set seed in the border area were missed during the post-emergence herbicide applications.

It is important to note that there was no loss of containment through pollen flow to other wheat, since the nearest wheat to the volunteer wheat plants is more than 600 feet. (Monsanto's current Field Release Performance Standard for wheat requires 33 feet isolation distance.)

Monsanto is taking the following precautionary actions with regard to this trial area:

- 1) The experimental area is now planted to soybeans and these can be harvested, but monitoring must occur immediately before harvest to ensure no volunteers are present during the harvest process. Prior to harvest the cooperator must supply written certification to Monsanto that no wheat volunteers are present in the trial area.



- 2) Volunteer monitoring of the entire plot area at monthly intervals will continue for a period of two years from the date that these volunteers were discovered.
- 3) No conventional wheat will be planted in the plot area for a period of two years from the date that these volunteers were discovered.
- 4) Commercial crops planted in the trial area during the two-year volunteer monitoring period can also be harvested, provided there is written certification that the trial is free of volunteers before harvesting.

While Monsanto regrets that the wheat volunteers were not removed prior to seed set, we are confident that there was no release to the environment, and that the steps we have outlined will assure proper handling of any regulated wheat plant material in the trial area.

As a follow up to this incident, all wheat cooperators will be contacted and reminded of the importance of timely removal of volunteer plants during the volunteer monitoring period.

Please call if you require further information concerning this matter.

Sincerely yours,

(b) (6), (b) (7)(C), (b) (4)





**CBI-DELETED**

MONSANTO COMPANY

800 NORTH LINDBERGH BOULEVARD

ST. LOUIS, MISSOURI 63167

PHONE (314) 694-1000

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August 30, 2005

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Please call if you require further information concerning this matter.

Sincerely yours,

[ CBI-DELETED ] - CBI

MONSANTO



From: Origin ID: (314)694-5273

MONSANTO  
800 North Lindbergh Blvd

Saint Louis, MO 63167



CL506135/09/13

Ship Date: 30AUG05  
Actual Wgt: 1 LB  
System#: 2032305/INET2200  
Account#: S \*\*\*\*\*

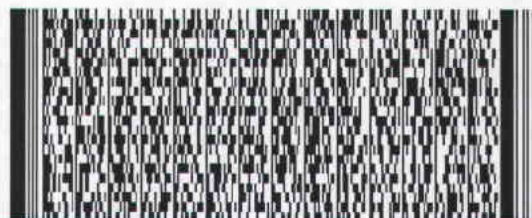
REF: 5180911542102300SLB76551



Delivery Address Bar Code

SHIP TO: (301)734-6356

BILL SENDER

Gregg Goodman  
USDA, APHIS, BRS  
Unit 147  
4700 River Road  
Riverdale, MD 20737

STANDARD OVERNIGHT

WED

TRK# 7917 1613 3636

FORM  
0201Deliver By:  
31AUG05

BWI A2

20737 -MD-US

NL GBOA



Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning:** Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on [fedex.com](http://fedex.com). FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.









United States  
Department of  
Agriculture

September 16, 2005

Animal and  
Plant Health  
Inspection  
Service

Marketing &  
Regulatory  
Programs Business  
Services

4700 River Road  
Riverdale, MD  
20737

(b) (6), (b) (7)(C), (b) (4)

Monsanto Company  
800 North Lindbergh Boulevard, B1NC  
St. Louis, Missouri 63167

Dear (b) (6), (b) (7)(C), (b) (4)

This acknowledges your August 30, 2005, letter to the Biotechnology Regulatory Services (BRS). You reported that Monsanto was unable to destroy volunteers before viable seed was produced for wheat regulated under Notification 03-058-02n. You reported similar incidents to BRS previously.

Although we note that Monsanto investigated and implemented corrective measures to manage this incident, we also note that additional surveillance immediately following destruction of the 2-leaf stage plants may have identified volunteers earlier. BRS may conduct future inspections to assess these corrective measures and verify that you comply with federal regulations.

We appreciate Monsanto's cooperation in voluntarily disclosing and correcting deviations at its facilities. If you have questions, please contact me at gregg.b.goodman@aphis.usda.gov or by telephone at (301) 734-6356.

Sincerely,

(b) (6), (b) (7)(C)

Gregg B. Goodman  
Compliance Officer  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
4700 River Rd.  
Riverdale, MD 20737



Date Draft: 9/16/05 *JS*  
Date Rev: 9/19/05 *JS*  
Date Final:  
Date Rev: *fw 9/19/05*



<b>Compliance Tracking</b>	20050072
<b>Permit_Number</b>	03-058-02n
<b>Organization</b>	Monsanto
<b>Permit (P)/ Notificat</b>	n
<b>Crop</b>	wheat
<b>Reported Self (S)/ In</b>	S
<b>Date Reported</b>	8/29/2005
<b>Incident Description</b>	Volunteer discovery.
<b>CFR violation</b>	7 CFR 340.3
<b>BRS Action</b>	GL
<b>IES Referral Yes (Y)</b>	<input type="checkbox"/>
<b>IES Action</b>	
<b>IES Action Completio</b>	
<b>IES Penalty/ Stipulat</b>	
<b>BRS Completion Date</b>	9/16/2005
<b>Notes</b>	Volunteers found (growing in boarder area for ~3-4 months and not devitalized). Initially from this '03 trial. Voicemail by (b) (6), (b) (7)(C), (b) (4) on 8/29/05. Letter with anything addl. To follow (per (b) (6), (b) (7)(C), (b) (4)). GGoodman 8-30-05.
<b>Final Resolution Date</b>	9/19/2005



<b>Compliance Tracking</b>	20050072
<b>Permit_Number</b>	03-058-02n
<b>Organization</b>	Monsanto
<b>Permit (P)/ Notificat</b>	n
<b>Crop</b>	wheat
<b>Reported Self (\$)/ In</b>	S
<b>Date Reported</b>	8/29/2005
<b>Incident Description</b>	Volunteer discovery.
<b>CFR violation</b>	7 CFR 340.3
<b>BRS Action</b>	GL
<b>IES Referral Yes (Y)</b>	<input type="checkbox"/>
<b>IES Action</b>	
<b>IES Action Completio</b>	
<b>IES Penalty/ Stipulat</b>	
<b>BRS Completion Date</b>	
<b>Notes</b>	Volunteers found (growing in boarder area for ~3-4 months and not devitalized). Initially from this '03 trial. Voicemail by (b) (6), (b) (7)(C), (b) (7)(D) on 8/29/05. Letter with anything addl. To follow (per (b) (6), (b) (7)(C), (b) (7)(D) GGoodman 8-30-05.
<b>Final Resolution Date</b>	



3/03/03 12:23 pm

Notification Tracking Sheet

=====

Bp number: 03-059-05n

=====

App number: 2003-262XRAB  
Received: 2/28/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 3/30/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.  
Address3:  
Address4:  
City/State/Zip: Chesterfield, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 3/29/03  
End movement: 3/29/04  
Begin release: 3/29/03  
End release: 3/29/04  
Acre: 10.00  
CBI status: CBI  
Fax: 636-737-7085

- |  | Initial         | Date        |
|--|-----------------|-------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>aid</i> ]  | [ 3/4/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>mfg</i> ]* | [ 3/4/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KZL</i> ]  | [ 3/5/03 ]* |
| 4. [ ] State response  |                 |             |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*ND	*	*SCR *
Interstate	*Orig*SD	*	*SCR *
Release	* *ND	*	1*SCR *

- |   |                |              |
|---|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database  | [ <i>aid</i> ] | [ 3/4/03 ]   |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw  | [ <i>KZL</i> ] | [ 3/21/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database   | [ <i>KZL</i> ] | [ 3/24/03 ]  |
| 8. [ ] If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |              |



MONSANTO



*CONFIDENTIAL*

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-262XRAB

Permit Unit

February 27, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-059-05n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-262XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2003 - March 29, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Oxen



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-262XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-262XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

30,000 30,000

### ORIGIN:

KS, ND, SD

### DESTINATION:

KS, ND, SD

### Ship From/Ship To:

KS

\* (b) (4) Sedgwick County/Province, KS, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)  
J-CBI

ND

\* (b) (4) Cass County/Province, ND, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.  
J-CBI

\* (b) (4) Cass County/Province,  
ND, (b) (4) U.S.A.  
CONTACT: (b) (4), (b) (6), (b) (7)(C)  
 Fargo, ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.  
J-CBI

SD

\* (b) (4) Brookings  
County/Province, SD, (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-262XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

J-CBI



*CONFIDENTIAL*

Monsanto Reference ID  
2003-262XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND(1)

ND

(b) (4) Cass County/Province, ND (b) (4) USA, 10  
acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-262XRAB

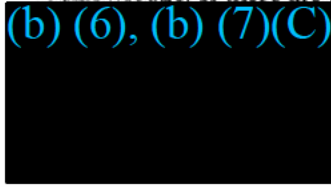
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 27, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-262XRAB

Permit Unit

February 27, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-059-05n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-262XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release March 29, 2003 - March 29, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-262XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-262XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction**      Interstate Movement and Release

30,000 30,000

#### **ORIGIN:**

KS, ND, SD

#### **DESTINATION:**

KS, ND, SD

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A

##### **SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-262XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND(1)

**ND**

[ CBI Deleted ] -- Cass County/Province, ND, USA, 10 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-262XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 27, 2003



MONSANTO



*CBI-DELETED*

Monsanto Reference ID  
2003-262XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

February 27, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-059-05n

1. USDA Reference Number

2. Application Reference Number 2003-262XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 29, 2003 - March 29, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen



## *CBI-DELETED*

Monsanto Reference ID  
2003-262X~~R~~AB

designation of transformed line: 33391

Constructs: PV-TXGT10

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### GENE OF INTEREST

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## CBI-DELETED

Monsanto Reference ID  
2003-262XRAB

### 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/15	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### 8. Introduction Interstate Movement and Release

30,000 30,000

#### ORIGIN:

KS, ND, SD

#### DESTINATION:

KS, ND, SD

#### Ship From/Ship To:

KS

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

ND

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A

SD

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

Monsanto Reference ID  
2003-262XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1)

ND

[ CBI Deleted ] -- Cass County/Province, ND, USA, 10 acres.



MONSANTO



*CBI-DELETED*


Monsanto Reference ID:  
2003-262X TAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 27, 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 3, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010658



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 3, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010659



file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

March 3, 2003

Dear Mr. Nelson:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010660



file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 3, 2003

Dear Mr. Fridley:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010661





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverview, Maryland  
20737-1200

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 3, 2003



Dear Mr. Fridley:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/6/03

State: South Dakota

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

March 3, 2003

Dear Mr. Nelson:

Enclosed is notification 03-059-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	03-059-05n	Applicant #:	2003-262XRAB
Received:	February 28, 2003	Effective:	March 30, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. *Supplemental conditions letter March 12 2003*

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *David R. Nelson*

Signature: (b) (6), (b) (7)(C)

Date: *3/12/03*

State: *ND*

Rptloc01/R4



March 21, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 30, 2003.

Interstate movement and Release  
Notification no. 03-059-05n (2003-262XRAB)  
Regulated article - Wheat  
Destinations - Kansas, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (letter attached dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
File number 03-059-05n

OR120018\_BR\_010664



AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
Biotechnology Program Operations – Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale MD 27037

FROM: David R. Nelson

DATE: March 12, 2003

RE: Supplemental Conditions for Release of Wheat  
Bp 03-015-10n  
Bp 03-052-27n  
Bp 03-052-59n  
Bp 03-059-05n

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

**North Dakota Supplemental Conditions 2003**

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

OR120018\_BR\_010665



Confirmation Report-Memory Send

Time : Mar-24-03 09:05am  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 009  
Date : Mar-24 09:04am  
To : 916367377085  
Document Pages : 02  
Start time : Mar-24 09:04am  
End time : Mar-24 09:05am  
Pages sent : 02  
Job number : 009

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

March 21, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 30, 2003.

Interstate movement and Release  
Notification no. 03-059-05n (2003-262XRAB)  
Regulated article - Wheat  
Destinations - Kansas, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (letter attached dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:  
T. Sim, Kansas State Board of Agric., Topeka, KS  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010666



*No CBI*

**2003 Wheat Field Test Report**  
**USDA #03-059-05n** **Monsanto #2003-262XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317549	Cass	ND	Not Planted

apl  
2/18/04



3/07/03 12:03 pm

## Notification Tracking Sheet

=====

Bp number: 03-064-09n

=====

App number: 2003-274XRAB  
 Received: 3/05/03  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 4/04/03  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person:  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)  
 Begin movement: 4/03/03  
 End movement: 4/03/04  
 Begin release: 4/03/03  
 End release: 4/03/04  
 Acre: 5.00  
 CBI status: CBI  
 Fax: 636-737-7085

- |  | Initial | Date          |
|--|---------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ aid ] | [ 3/10/03 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ KS ]* | [ 03-10-03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ K&Q ] | [ 3/12/03 ]*  |
| 4. <input type="checkbox"/> State response                                     |         |               |

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*SCR *
Interstate	*Dest*	MO	*SCR *
Interstate	*Dest*	MT	*WR *
Interstate	*Orig*	KS	*SCR *
Interstate	*Orig*	MO	*SCR *
Interstate	*Orig*	MT	*WR *
Release	*	*MT	* 1*WR *

- |  |         |              |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ aid ] | [ 3/10/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ K&Q ] | [ 3/27/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ K&Q ] | [ 3/28/03 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |         |              |



*CONFIDENTIAL***MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-274XRAB

Permit Unit

March 4, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-064-09n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-274XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 3, 2003 - April 3, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-274XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-274XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

20,000 pounds Ship up to 20,000 pounds wheat seed to and from each location.

### ORIGIN:

KS, MO, MT

### DESTINATION:

KS, MO, MT

### Ship From/Ship To:

KS

\* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

\* (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MT

\* (b) (4), (b) (6), (b) (7)(C) Toole County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4) Cascade County/Province, MT (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-274XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-274XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(1)

MT

(b) (4), (b) (6), (b) (7)(C) Toole County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI



MONSANTO



*CONFIDENTIAL*

Monsanto Reference ID  
2003-274XRAB


**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 4, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

March 4, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-064-09n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-274XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 3, 2003 - April 3, 2004

**5. Recipient**

Wheat, *Triticum aestivum*

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## *CBI-DELETED*

### **Monsanto Reference ID**

2003-274XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

### **Monsanto Reference ID**

2003-274XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 pounds Ship up to 20,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MO, MT

#### **DESTINATION:**

KS, MO, MT

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Toole County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(1)

**MT**

[ CBI Deleted ] -- Toole County/Province, MT, USA, 5 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 4, 2003



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
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**Monsanto Reference ID**  
2003-274XRAB

Permit Unit

March 4, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-064-09n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-274XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 3, 2003 - April 3, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 pounds Ship up to 20,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MO, MT

#### **DESTINATION:**

KS, MO, MT

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Toole County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-274XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(1)

**MT**

[ CBI Deleted ] -- Toole County/Province, MT, USA, 5 acres.



MONSANTO



*CBI-DELETED*

Monsanto Reference ID  
2003-274XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 4, 2003



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 7, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-064-09n	Applicant #:	2003-274XRAB
Received:	March 5, 2003	Effective:	April 4, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010688



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 7, 2003

Dear Mr. Brown:

Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-064-09n	Applicant #:	2003-274XRAB
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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

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\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010689





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 7, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010690





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 7, 2003

Dear Mr. Brown:

Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4





file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 7, 2003

Dear Mr. Ames:


Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-064-09n	Applicant #:	2003-274XRAB
Received:	March 5, 2003	Effective:	April 4, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010692





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 7, 2003

Dear Mr. Ames:

Enclosed is notification 03-064-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-064-09n	Applicant #:	2003-274XRAB
Received:	March 5, 2003	Effective:	April 4, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 3/21/03

State: Montana

Rptloc01/R4





March 27, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway W.  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 4, 2003.

Interstate movement and Release  
Notification no. 03-064-09n (2003-274XRAB)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
File number 03-064-09n

OR120018\_BR\_010694



# Confirmation Report-Memory Send

Time : Mar-27-03 04:15pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 087  
Date : Mar-27 04:15pm  
To : 916367377085  
Document Pages : 01  
Start time : Mar-27 04:15pm  
End time : Mar-27 04:15pm  
Pages sent : 01  
Job number : 087

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1536

March 27, 2003

(b) (6), (b) (7)(C)

Montanto Company  
700 Chesterfield Parkway W.  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 4, 2003.

Interstate movement and Release  
Notification no. 03-054-02n (2003-2743RAB)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010695





United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Plant Protection and Quarantine



USDA, APHIS, PPQ  
1220 Cole Ave.  
Helena, MT 59601  
(406) 449-5210  
Fax: 449-5212

Federal Relay Service (Voice/TTY/ASCII/Spanish) 800-877-8339

**Subject:** Notification Field Site Inspection (# 03-064-09n)

**Date:** September 4, 2003

**To:** Juan A. Roman, Chief, Biotechnology Program Operations  
USDA APHIS BRS  
4700 River Rd. Unit 147, 5B53  
Riverdale MD 20737

On 12 August 2003, a representative of the Montana Department of Agriculture and I conducted a Notification Field Site Inspection at the (b) (6), (b) (7)(C), (b) (4) MT (site # 03-064-09n).

Prior to the inspection I called (b) (6), (b) (7) Monsanto Company, (b) (4) MT 59404, (406) 771-1920. He was out of state and unable to accompany us on the inspection. He informed me that the test plot of non-hybrid Roundup resistant wheat would be harvested early next week (approx. 8/18-23/03). The seeds had arrived in double wrapped containers that were locked in his storage shed until used. Any remaining seed and the shipping containers were incinerated. He faxed site specific protocols, directions to the site, and a note stating approx. 4 head of cattle had been in the test plot a few weeks earlier, and the Monsanto Compliance Person had been notified. We were unaccompanied on the inspection.

The test plot was approximately 2 acres square, marked with metal posts, not irrigated and buffered by 10 meters of fallow. No sexually compatible plants were nearby. The surrounding crop was barley that had been recently harvested and pasture. No volunteer wheat was noted. There were a few tracks indicating where cattle had been in the plot but no cattle were present during the inspection. (b) (6), stated that the test plot would be fallowed and monitored for volunteers for 2 years after harvest.

On the basis of examination, conversation with (b) (6), (b) (7), I believe the Performance Standards have been met (please see enclosure).

(b) (6), (b) (7)(C)

Richard "Joe" Merenz  
Domestic Program Coordinator, Montana

**Enclosure: NOTIFICATION FIELD SITE INSPECTION WORKSHEET**

cc: Ralph Stoaks, Regional Program Manager  
Gary Adams, State Plant Health Director, Montana  
Kimberly Merenz, Quarantine/Nursery Specialist, MDA



# NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): 03-064-09 n

Crop: Wheat (non hybrid)

Applicant's Name: (b) (6), (b) (7)(C)

Trait/Gene: Glyphosate Tolerant

Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4)

Location of Site: (b) (6), (b) (7)(C), (b) (4) MT

Date of Inspection: 8/12/03

Type of Location: Farm ☒ Nursery ☐ Research ☐ Other ☐ (Describe) \_\_\_\_\_

GPS Coordinates (If available): Latitude \_\_\_\_\_ Longitude \_\_\_\_\_

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

## I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? ☒ Y ☐ N
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? ☒ Y ☐ N

## II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? ☒ Y ☐ N
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? ☒ Y ☐ N
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- \_\_\_\_\_ 1. Removing flowers.  
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? ☐ Y ☐ N
- \_\_\_\_\_ 2. Bagging flowers/tassels  
C.2. Does the applicant have material to bag reproductive structures? ☐ Y ☐ N
- \_\_\_\_\_ 3. Terminating the experiment before flowering.  
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? ☐ Y ☐ N
- ☒ 4. Physical isolation.  
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? ☒ Y ☐ N
- \_\_\_\_\_ 5. Temporal isolation.  
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? ☐ Y ☐ N



D. If the applicant's design standards use border rows, are there the state number of border rows?

Y

N

NA

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species?

Y

N

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards?

Y

N

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards?

Y

N

H. Was the field site marked as stated in the design standards?

Y

N

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts?

Y

N

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive?

Y

N

### III. Devitalization.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)?

Y

N

B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer:

(b) (6), (b) (7)(C)

Phone:

(406) 449-5210

Location of PPQ Office

Helena MT

Names and Affiliation of Any Other Persons at the Inspection:

Kimberly Maranz

Quarantine/Nursery Specialist

MT Dept of Agriculture

P.O. Box 200201

Helena MT 59601

(406) 444-9066

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-064-09n** **Monsanto #2003-274XRAB**

**March 2, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

**Location**  
2147317763

**County**  
Toole

**State**  
MT

**Toole County/MT (2147317763)**

(b) (4)

apl  
3/3/04



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-064-09n**                      **Monsanto #2003-274XRAB**

**March 2, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317763	Toole	MT

**Toole County/MT (2147317763)**

**Planting Date:** 04/22/2003

**Harvest Date:** 08/14/2003

**Destruct Date:** 08/28/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]



3/14/03 11:28 am

Notification Tracking Sheet

=====  
Bp number: 03-071-06n  
=====

App number: 2003-284XRAB  
Received: 3/12/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 4/11/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.  
Address3:  
Address4:  
City/State/Zip: Chesterfield, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 4/10/03  
End movement: 4/10/04  
Begin release: 4/10/03  
End release: 4/10/04  
Acre: 10.00  
CBI status: CBI  
Fax: 636-737-7085

- =====
- |  | Initial         | Date         |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]  | [ 3/14/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>AMK</i> ]* | [ 3/17/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed ex</i> | [ <i>KLO</i> ]  | [ 3/17/03 ]* |
| 4. <input type="checkbox"/> State response   |                 |              |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[ ]
Interstate	*Dest*	MO	*	*SCR	*	[ ]
Interstate	*Dest*	MT	*	*WR	*	[ ]
Interstate	*Dest*	ND	*	*SCR	*	[ ]
Interstate	*Dest*	SD	*	*SCR	*	[ ]
Interstate	*Orig*	KS	*	*SCR	*	[ ]
Interstate	*Orig*	MO	*	*SCR	*	[ ]
Interstate	*Orig*	MT	*	*WR	*	[ ]
Interstate	*Orig*	ND	*	*SCR	*	[ ]
Interstate	*Orig*	SD	*	*SCR	*	[ ]
Release	*	*ND	*	1*SCR	*	[ ]

- =====
- |  |                |              |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajd</i> ] | [ 3/17/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KLO</i> ] | [ 4/11/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KLO</i> ] | [ 4/18/03 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |              |

OR120018\_BR\_010704



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-284XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

March 11, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-071-06n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-284XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

April 10, 2003 - April 10, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-284XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



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## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the duration of this notification. Ship up to 1000 pounds wheat seed to and from each location.

### ORIGIN:

KS, MO, MT, ND, SD

### DESTINATION:

KS, MO, MT, ND, SD

### Ship From/Ship To:

KS

(b) (4) Harvey County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Wichita, KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

\* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MT

(b) (4) Cascade County/Province, MT (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-284XRAB

CONTACT: Douglas Ryerson, Monsanto Company, 408 Deer Drive, Great Falls, MT, 59404, USA,  
406/771-1920

] -CBI

ND

\* [REDACTED] (b) (4) Burke County/Province, ND, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) ND, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* [REDACTED] (b) (4) Burke County/Province, ND, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) ND, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

\* [REDACTED] (b) (4) Brookings  
County/Province, SD, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) SD, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-284XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND(1)

ND

(b) (4) Burke County/Province, ND (b) (4) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

J-CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-284XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 11, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

March 11, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-071-06n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-284XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 10, 2003 - April 10, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the duration of this notification. Ship up to 1000 pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MO, MT, ND, SD

#### **DESTINATION:**

KS, MO, MT, ND, SD

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Harvey County/Province, KS, USA

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

##### **ND**

[ CBI Deleted ] -- \*Burke County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Burke County/Province, ND, USA

##### **SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND(1)

**ND**

[ CBI Deleted ] -- Burke County/Province, ND, USA, 10 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

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CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 11, 2003



MONSANTO



*CBI-DELETED*

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Permit Unit

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Riverdale, MD 27037

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**1. USDA Reference Number**

**2. Application Reference Number** 2003-284XRAB

**3. Application/Responsible Party**

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Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 10, 2003 - April 10, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite



## *CBI-DELETED*

### **Monsanto Reference ID**

2003-284XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the duration of this notification. Ship up to 1000 pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MO, MT, ND, SD

#### **DESTINATION:**

KS, MO, MT, ND, SD

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Harvey County/Province, KS, USA

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

##### **ND**

[ CBI Deleted ] -- \*Burke County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Burke County/Province, ND, USA

##### **SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-284XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND(1)

**ND**

[ CBI Deleted ] -- Burke County/Province, ND, USA, 10 acres.



MONSANTO



*CBI-DELETED*

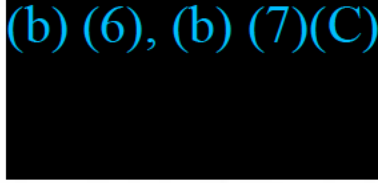
**Monsanto Reference ID**  
2003-284XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 11, 2003



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 14, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010724



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 14, 2003

Dear Mr. Brown:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010725



file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 14, 2003

Dear Mr. Ames:


Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010726



file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

March 14, 2003

Dear Mr. Nelson:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010727



file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 14, 2003

Dear Mr. Fridley:


Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010728





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 14, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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United States  
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Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 14, 2003

Dear Mr. Brown:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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Plant Health  
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Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 14, 2003

Dear Mr. Ames:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-071-06n	Applicant #:	2003-284XRAB
Received:	March 12, 2003	Effective:	April 11, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date: 3/21/03

State: Montana

Rptloc01/R4



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OR120018\_BR\_010731

MAR 21 2003





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Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

March 14, 2003

Dear Mr. Nelson:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-071-06n Applicant #: 2003-284XRAB  
Received: March 12, 2003 Effective: April 11, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: KS MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. w/ Supplemental Conditions letter  
March 24, 2003

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-24-03

State: ND

Rptloc01/R4



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Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

March 14, 2003

Dear Mr. Nelson:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-071-06n Applicant #: 2003-284XRAB  
Received: March 12, 2003 Effective: April 11, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: KS MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. *W/ Supplemental Conditions letter*  
*March 24, 2003*  
☐ State DOES NOT CONCUR and offers the following reasons:  
Name of State official: *R Nelson*  
Signature: (b) (6), (b) (7)(C)  
Date: *3-24-03*  
State: *ND*

Rptloc01/R4



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MAR 24 2003

OR120018\_BR\_010733





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

March 14, 2003

Dear Mr. Fridley:

Enclosed is notification 03-071-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Sp number 03-071-06n Applicant #: 2003-284XRAB  
Received: March 12, 2003 Effective: April 11, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: KS MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, FPO, Fort Collins, CO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/18/03

State: South Dakota

Rptloc01/R4



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MAR 19 2003

OR120018\_BR\_010734



April 11, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 11, 2003.

Interstate movement and Release

Notification no. 03-071-06n (2003-284XRAB)

Regulated article - Wheat

Destinations - Kansas, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (see letter dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
File number 03-071-06n

OR120018\_BR\_010735



AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
Biotechnology Program Operations – Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale MD 27037

FROM: David R. Nelson

DATE: March 12, 2003

RE: Supplemental Conditions for Release of Wheat  
Bp 03-071-06n  
Bp 03-073-03n

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

**North Dakota Supplemental Conditions 2003**

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat, or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

OR120018\_BR\_010736



Confirmation Report-Memory Send

Time : Apr-16-03 10:25am  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 554  
Date : Apr-16 10:24am  
To : 916367377085  
Document Pages : 02  
Start time : Apr-16 10:24am  
End time : Apr-16 10:25am  
Pages sent : 02  
Job number : 554

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

April 11, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 11, 2003.

Interstate movement and Release

Notification no. 03-071-06a (2003-284XRAB)

Regulated article - Wheat

Destinations - Kansas, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (see letter dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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OR120018\_BR\_010737



*No CBI*

**2003 Wheat Field Test Report**  
**USDA #03-071-06n** **Monsanto #2003-284XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317842	Burke	ND	Not Planted

ad  
2/18/04



3/27/03 1:02 pm

Notification Tracking Sheet

=====  
Bp number: 03-080-02n  
=====

App number: 2003-298XRAB  
Received: 3/21/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 4/20/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: (b) (6), (b) (7)(C)  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.  
Address3:  
Address4:  
City/State/Zip: Chesterfield, MO 63198  
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085  
=====

- |  | Initial         | Date         |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>aid</i> ]  | [ 3/28/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>gmc</i> ]* | [ 3/28/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>Kxno</i> ] | [ 4/1/03 ]*  |
| 4. [ ] State response  |                 |              |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[ ]
Interstate	*Dest*	MO	*	*SCR	*	[ ]
Interstate	*Dest*	MT	*	*WR	*	[ ]
Interstate	*Orig*	KS	*	*SCR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Interstate	*Orig*	MT	*	*WR	*	
Release	*	*MT	*	1*WR	*	[ ]

- |   |                 |              |
|---|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database  | [ <i>aid</i> ]  | [ 3/28/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw  | [ <i>Kxno</i> ] | [ 4/14/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database   | [ <i>Kxno</i> ] | [ 4/16/03 ]  |
| 8. [ ] If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                 |              |



*CONFIDENTIAL***MONSANTO COMPANY**700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>**Monsanto Reference ID**  
2003-298XRAB

Permit Unit

March 19, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-080-02n

**1. USDA Reference Number****2. Application Reference Number** 2003-298XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 18, 2003 - April 18, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-298XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

*CBI*

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-298XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

20,000 pounds Ship up to 20,000 pounds wheat seed to and from each location.

### ORIGIN:

KS, MO, MT

### DESTINATION:

KS, MO, MT

### Ship From/Ship To:

KS

\* (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

\* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MT

\* (b) (4), (b) (6), (b) (7)(C) Hill County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\* (b) (4) Cascade County/Province, MT (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-298XRAB

CONTACT (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-298XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(1)

**MT**

[ (b) (4), (b) (6), (b) (7)(C) Hill County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA, 5 acres. (b) (4), (b) (6), (b) (7)(C)

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-298XRAB

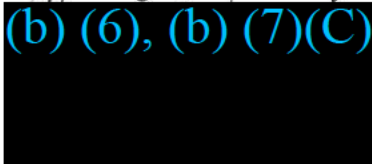
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 19, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-298XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

March 19, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-080-02n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-298XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release April 18, 2003 - April 18, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-298XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-298XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 pounds Ship up to 20,000 pounds wheat seed to and from each location.

#### **ORIGIN:**

KS, MO, MT

#### **DESTINATION:**

KS, MO, MT

#### **Ship From/Ship To:**

##### **KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Hill County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-298XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(1)

**MT**

[ CBI Deleted ] -- Hill County/Province, MT, USA, 5 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-298XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 19, 2003



MONSANTO



CBI-DELETED

Monsanto Reference ID  
2003-298XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 19, 2003

1. USDA Reference Number

03-080-02n

2. Application Reference Number 2003-298XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

April 18, 2003 - April 18, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): McNeal



## CBI-DELETED

Monsanto Reference ID  
2003-298XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

### GENE OF INTEREST

Promoter: CMOVa/I2 -- [ CBI Deleted ]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



*CBI-DELETED*

Monsanto Reference ID  
2003-298XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(1)

MT

[ CBI Deleted ] -- Hill County/Province, MT, USA, 5 acres.



MONSANTO



*CBI-DELETED*

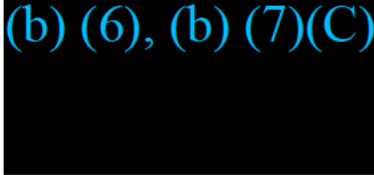
Monsanto Reference ID  
2003-298XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 19, 2003



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 27, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-080-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-080-02n	Applicant #:	2003-298XRAB
Received:	March 21, 2003	Effective:	April 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010758



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 27, 2003

Dear Mr. Brown:

Enclosed is notification 03-080-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-080-02n	Applicant #:	2003-298XRAB
Received:	March 21, 2003	Effective:	April 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010759



file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 27, 2003

Dear Mr. Ames:


Enclosed is notification 03-080-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-080-02n	Applicant #:	2003-298XRAB
Received:	March 21, 2003	Effective:	April 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010760





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 27, 2003

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Bp number	03-080-02n	Applicant #:	2003-298XRAB
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Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010761





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 27, 2003

Dear Mr. Brown:

Enclosed is notification 03-080-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Received:	March 21, 2003	Effective:	April 20, 2003
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Interstate destination:	KS MO MT		
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Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010762





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

March 27, 2003

Dear Mr. Ames:

Enclosed is notification 03-080-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-080-02n	Applicant #:	2003-298XRAB
Received:	March 21, 2003	Effective:	April 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION



State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 4/3/03

State: Montana

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010763

APR 3 2003



April 14, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway W.  
Chesterfield, MO 63017

(b) (6), (b) (7)(C)

Dear [REDACTED]

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 20, 2003.

Interstate movement and Release  
Notification no. 03-080-02n (2003-298XRAB)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
File number 03-080-02n

OR120018\_BR\_010764



Confirmation Report-Memory Send

Time : Apr-14-03 04:40pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 509  
Date : Apr-14 04:39pm  
To : 916367377085  
Document Pages : 01  
Start time : Apr-14 04:39pm  
End time : Apr-14 04:40pm  
Pages sent : 01

Job number : 509

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

April 14, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway W.  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 20, 2003.

Interstate movement and Release  
Notification no. 03-080-02n (2003-2963RAP)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010765



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-080-02n** **Monsanto #2003-298XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

Location  
2147317902

County  
Hill

State  
MT

Hill County/MT (2147317902)

(b) (4)

apl  
2/18/04



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-080-02n**                      **Monsanto #2003-298XRAB**

**February 17, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317902	Hill	MT

Hill County/MT (2147317902)

**Planting Date:** 04/23/2003

**Harvest Date:** 08/07/2003

**Destruct Date:** 09/03/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]





United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Plant Protection and Quarantine



Federal Relay Service (Voice/TTY/ASCII/Spanish) 800-877-8339

USDA, APHIS, PPQ  
1220 Cole Ave.  
Helena, MT 59601  
(406) 449-5210  
Fax: 449-5212

**Subject:** Notification Field Site Inspection (# 03-080-02n)

**Date:** September 4, 2003

**To:** Juan A. Roman, Chief, Biotechnology Program Operations  
USDA APHIS BRS  
4700 River Rd. Unit 147, 5B53  
Riverdale MD 20737

9/10/03

On 12 August 2003, a representative of the Montana Department of Agriculture and I conducted a Notification Field Site Inspection at the (b) (4), (b) (6), (b) (7)(C) MT (site # 03-080-02n).

Prior to inspection, I called (b) (6), (b) (7)(C) Monsanto Company, 408 Deer Drive, Great Falls MT 59404 (b) (6), (b) (7)(C). He was out of state and unable to accompany us on the inspection. He informed me that the test plot of non-hybrid Roundup resistant wheat had been harvested on 07 August 2003 and would be tilled early next week. The seeds had arrived in double wrapped containers that were locked in his storage shed until used. Any remaining seed and the shipping containers were incinerated after the tests. He also faxed site specific protocols and directions to the farm where we were met by (b) (4), (b) (6), (b) (7)(C).

The test plot was approximately 2 acres square, marked with metal posts, and buffered by 10 meters of fallow. No sexually compatible plants were nearby. The surrounding crop was barley and we were informed by (b) (4), (b) (6), (b) (7)(C) "...the barley will be in fallow next year." No volunteers were noted, but there were viable seeds on the ground. (b) (4), (b) (6), (b) (7)(C) assured us the seed would be disc'd in next week and (b) (6), (b) (7)(C) reaffirmed his statement in a later phone conversation. (b) (6), (b) (7)(C) also stated that the test plot would be fallowed and monitored for volunteers for 2 years.

On the basis of examination, conversation with (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) I believe the Performance Standards have been met (please see enclosure). Because of the viable seeds noted on the ground during this examination, another visit next spring is warranted.

(b) (6), (b) (7)(C)

Richard "Joe" Merenz  
Domestic Program Coordinator, Montana

Enclosure: NOTIFICATION FIELD SITE INSPECTION WORKSHEET

cc: Ralph Stoaks, Regional Program Manager  
Gary Adams, State Plant Health Director, Montana  
Kimberly Merenz, Quarantine/Nursery Specialist, MDA



# NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): 03-080-02n Crop: Wheat (Non hybrid)  
Applicant's Name: (b) (6), (b) (7)(C) Trait/Gene: Glyphosate Tolerant  
Name of Cooperator at Inspected Site: (b) (4), (b) (6), (b) (7)(C) Phone: (b) (4), (b) (6), (b) (7)(C)  
Location of Site: (b) (4), (b) (6), (b) (7)(C) MT Date of Inspection: 8/12/03  
Type of Location: Farm ☒ Nursery ☐ Research ☐ Other ☐ (Describe) \_\_\_\_\_  
GPS Coordinates (If available): Latitude \_\_\_\_\_ Longitude \_\_\_\_\_

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

## I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? (Y) N
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? (Y) N

## II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? (Y) N
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? (Y) N
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- \_\_\_\_\_ 1. Removing flowers.  
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N
- \_\_\_\_\_ 2. Bagging flowers/tassels  
C.2. Does the applicant have material to bag reproductive structures? Y N
- \_\_\_\_\_ 3. Terminating the experiment before flowering.  
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N
- ☒ 4. Physical isolation.  
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? (Y) N
- \_\_\_\_\_ 5. Temporal isolation.  
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N



D. If the applicant's design standards use border rows, are there the state number of border rows?

Y

N

NA

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species?

Y

N

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards?

Y

N

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards?

Y

N

H. Was the field site marked as stated in the design standards?

Y

N

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts?

Y

N

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive?

Y

N

### III. Devitalization.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)?

Y

N

B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer:

(b) (6), (b) (7)(C)

Phone:

(406) 449-5210

Location of PPQ Office

Helena MT

Names and Affiliation of Any Other Persons at the Inspection:

(b) (6), (b) (7)(C)

Quarantine/Nursery Specialist

MT Dept of Ag

P.O. Box 200201

Helena MT 59601

(406) 444-9066

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.



7/29/03 11:13 am

Notification Tracking Sheet

=====  
Bp number: 03-209-03n  
=====

App number: 2003-414XRAB  
Received: 7/28/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 8/27/03  
Phenotype: HT - Glyphosate tolerant  
Comments:

Begin movement: 8/24/03  
End movement: 8/24/04  
Begin release: 8/24/03  
End release: 8/24/04  
Acre: 5.00  
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)  
Parsed name:

Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:

City/State/Zip: St. Louis, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085  
=====

- |  | Initial        | Date          |
|--|----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajb</i> ] | [ 7/30/03 ]   |
| 2. <input type="checkbox"/> Review by biotechnologist                                | [ <i>AS</i> ]* | [ 07-30-03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLW</i> ] | [ 8/1/03 ]*   |
| 4. <input type="checkbox"/> State response   |                |               |

	O/d	Loc	Site	Reg				
Interstate	*Dest	*HI	*	*WR	*	[	]	[
Interstate	*Dest	*IA	*	*SCR	*	[	]	[
Interstate	*Dest	*ID	*	*WR	*	[	]	[
Interstate	*Dest	*KS	*	*SCR	*	[	]	[
Interstate	*Dest	*MN	*	*NER	*	[	]	[
Interstate	*Dest	*MO	*	*SCR	*	[	]	[
Interstate	*Dest	*MT	*	*WR	*	[	]	[
Interstate	*Dest	*ND	*	*SCR	*	[	]	[
Interstate	*Dest	*SD	*	*SCR	*	[	]	[
Interstate	*Dest	*WA	*	*WR	*	[	]	[
Interstate	*Orig	*HI	*	*WR	*			
Interstate	*Orig	*IA	*	*SCR	*			
Interstate	*Orig	*ID	*	*WR	*			
Interstate	*Orig	*KS	*	*SCR	*			
Interstate	*Orig	*MN	*	*NER	*			
Interstate	*Orig	*MO	*	*SCR	*			
Interstate	*Orig	*ND	*	*SCR	*			
Interstate	*Orig	*SD	*	*SCR	*			
Interstate	*Orig	*WA	*	*WR	*			
Release	*	*HI	*	1*WR	*	[	]	[



7/29/03 11:13 am

Notification Tracking Sheet

=====  
Bp number: 03-209-03n  
=====

App number: 2003-414XRAB  
Received: 7/28/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 8/27/03  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: (b) (6), (b) (7)(C)  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085  
=====

	Initial	Date
1. [ ] Assign Bp number and initial data entry	[ ]	[ ]
2. [ ] Review by biotechnologist	[ ]*	[ ]*
3. [ ] Letter of notification to State	[ ]	[ ]*
4. [ ] State response		

O/d Loc Site Reg

5. [ ] Enter genes into database	[ ]	[ ]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[ KLn ]	[ 10/8/03 ]*
7. [✓] Enter final data into database	[ KLn ]	[ 10/9/03 ]
8. [ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

OR120018\_BR\_010775



MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-414XRAB

Permit Unit

July 25, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-209-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-414XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

August 24, 2003 - August 24, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-414XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) (h) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-414XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

Ship up to 20,000 lbs of wheat seed to/from each location.

### ORIGIN:

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

### DESTINATION:

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

### Ship From/Ship To:

HI

\* [REDACTED] (b) (4) Honolulu  
County/Province, (b) (4) HI, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* [REDACTED] (b) (4) Honolulu  
County/Province, (b) (4) HI, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

IA

\* [REDACTED] (b) (4) Ames, Story County/Province, IA, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) IA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

ID



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-414XRAB

\* [REDACTED] (b) (4) Bingham  
County/Province, ID (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) III (b) (4), (b) (6), (b) (7)(C)

] -CBI

KS

\* [REDACTED] (b) (4) Geary County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* [REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MN

\* [REDACTED] (b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* [REDACTED] (b) (4) Ramsey County/Province,  
MN (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C) J.S.A. [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

MO

\* [REDACTED] (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,



CONFIDENTIAL

Monsanto Reference ID  
2003-414XRAB

(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MT

\*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

\*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

ND

\*[(b) (4)] Cass  
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

\*[(b) (4)] Brookings  
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

\*[(b) (4)] Whitman  
County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-414XRAB

]CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-414XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI(1)

**HI**

(b) (4)  
County/Province, (b) (4) HI, (b) (4) USA, 5 acres. (b) (4) Honolulu

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-414XRAB

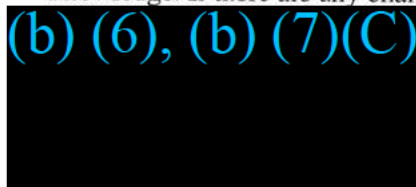
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 25, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-414XRAB

Permit Unit

July 25, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-209-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-414XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release August 24, 2003 - August 24, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

Ship up to 20,000 lbs of wheat seed to/from each location.

#### **ORIGIN:**

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

#### **DESTINATION:**

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

#### **Ship From/Ship To:**

##### **HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, USA

[ CBI Deleted ] -- \*Honolulu County/Province, HI, U.S.A.

##### **IA**

[ CBI Deleted ] -- \*Story County/Province, IA, U.S.A

##### **ID**

[ CBI Deleted ] -- \*Bingham County/Province, ID

##### **KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### **MN**

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI(1)

**HI**

[ CBI Deleted ] -- Honolulu County/Province, HI, USA, 5 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 25, 2003



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-414XRAB

Permit Unit

July 25, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-209-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-414XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

August 24, 2003 - August 24, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## CBI-DELETED

**Monsanto Reference ID**  
2003-414XRAB

### 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### 8. Introduction Interstate Movement and Release

Ship up to 20,000 lbs of wheat seed to/from each location.

#### ORIGIN:

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

#### DESTINATION:

HI, IA, ID, KS, MN, MO, MT, ND, SD,  
WA

#### Ship From/Ship To:

##### HI

[ CBI Deleted ] -- \*Honolulu County/Province, HI, USA

[ CBI Deleted ] -- \*Honolulu County/Province, HI, U.S.A.

##### IA

[ CBI Deleted ] -- \*Story County/Province, IA, U.S.A

##### ID

[ CBI Deleted ] -- \*Bingham County/Province, ID

##### KS

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

##### MN

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

##### MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### MT



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI(1)

**HI**

[ CBI Deleted ] -- Honolulu County/Province, HI, USA, 5 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-414XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 25, 2003



file copy

Dr. Neil Reimer, Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
1849 Auiki Street  
Honolulu, HI 96819-3100

July 29, 2003

Dear Dr. Reimer:


Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010799



file copy

Mr. Charles Stoltenow  
IA Department of Agriculture and Land Stewardship  
First Floor, Wallace building  
East 9th Street and Grand Avenue  
Des Moines, IA 50319

July 29, 2003

Dear Mr. Stoltenow:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

MS

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010800



file copy

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

July 29, 2003

Dear Mr. Cooper:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010801





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

July 29, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

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OR120018\_BR\_010802



file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

July 29, 2003

Dear Dr. Hanks:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010803





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

July 29, 2003

Dear Mr. Brown:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

July 29, 2003

Dear Ms. Witham:


Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010805



file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

July 29, 2003

Dear Mr. Nelson:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010806



file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

July 29, 2003

Dear Mr. Fridley:


Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010807



file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

July 29, 2003

Dear Mr. Wessels:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010808





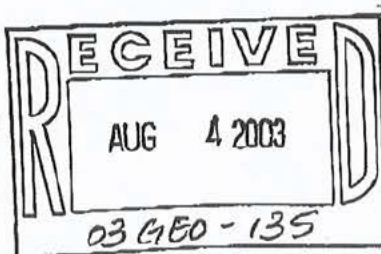
United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Neil Reimer, Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
1849 Auiki Street  
Honolulu, HI 96819-3100



July 29, 2003

Dear Dr. Reimer:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 1849 Auiki Honolulu, HI 96819.  
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol Okada

Signature: (b) (6), (b) (7)(C)

Date: 6 October 2003

State: Hawaii

Rptloc01/R4

\*The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.



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OR120018\_BR\_010809

OCT 7 2003





United States  
Department of  
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Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Charles Stoltenow  
IA Department of Agriculture and Land Stewardship  
First Floor, Wallace building  
East 9th Street and Grand Avenue  
Des Moines, IA 50319

July 29, 2003

Dear Mr. Stoltenow:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

  X   State concurs with APHIS determination.

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: C. R. Stoltenow

Signature: (b) (6), (b) (7)(C)

Date: AUGUST 11, 2003

State: IOWA

Rptloc01/R4



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AUG 11 2003

TOTAL P. 04





United States  
Department of  
Agriculture

Animal and  
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Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

July 29, 2003

RECEIVED

AUG 04 2003

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Cooper

Signature: (b) (6), (b) (7)(C)

Date: 8/4/03

State: IDAHO

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

July 29, 2003

Dear Dr. Hanks:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *movement only*  
\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *8-8-03*

State: *MN*

Rptloc01/R4



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AUG 8 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

July 29, 2003

Dear Ms. Witham:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-209-03n	Applicant #:	2003-414XRAB
Received:	July 28, 2003	Effective:	August 27, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI IA ID KS MN MO MT ND SD WA		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 8/4/03

State: Montana

Rptloc01/R4



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AUG 4 2003





United States  
Department of  
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Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

July 29, 2003

Dear Mr. Nelson:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 8-6-03

State: ND

Rpt.loc01/R4



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AUG 6 2003

OR120018\_BR\_010814





United States  
Department of  
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Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

July 29, 2003

Dear Mr. Fridley:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature:

(b) (6), (b) (7)(C)

Date: 8/4/03

State: South Dakota

Rptloc01/R4



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AUG 5 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

July 29, 2003

Dear Mr. Wessels:

Enclosed is notification 03-209-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-209-03n Applicant #: 2003-414XRAB  
Received: July 28, 2003 Effective: August 27, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI IA ID KS MN MO MT ND SD WA  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 8/4/03

State: WA

Rptloc01/R4



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OR120018\_BR\_010816

AUG 4 2003



October 8, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 8, 2003.

**Interstate movement and Release**

Notification no. 03-209-03n (2003-414XRAB)

Regulated article - Wheat

Destinations - Hawaii, Iowa, Idaho, Kansas, Minnesota, Missouri, Montana,  
North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination for movement only.

The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Ms. Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, at each of the following times:
  - a) All planting, pollinating and harvesting dates of each field trial.
  - b) Any changes to the field sites, recommended conditions, or other related matters.
  - c) The unplanned release or theft of any transgenic wheat plants or plant parts.

OR120018\_BR\_010817



3. Submit a written report on the field test data including information on:

- a) The germination of volunteer wheat after harvest.
- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than corn seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Dr. Neil Reimer, Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

N. Reimer, Hawaii Dept. of Agric., Honolulu, HI  
C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA  
M. Cooper, Idaho State Dept. of Agric., Boise, ID  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Hank, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
T. Wessels, Washington Dept. of Agric., Olympia, WA

File number 03-209-03n



# Confirmation Report-Memory Send

Time : Oct-08-03 03:53pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 559  
Date : Oct-08 03:51pm  
To : 916367377085  
Document Pages : 06  
Start time : Oct-08 03:51pm  
End time : Oct-08 03:53pm  
Pages sent : 06  
Job number : 559

\*\*\* SEND SUCCESSFUL \*\*\*



Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

October 8, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 8, 2003.

Interstate movement and Release  
Notification no. 03-209-03n (2003-414XRAB)  
Regulated article - Wheat

Destinations - Hawaii, Iowa, Idaho, Kansas, Minnesota, Missouri, Montana,  
North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination for movement only.

The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Ms. Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, at each of the following times:
  - a) All planting, pollinating and harvesting dates of each field trial.
  - b) Any changes to the field sites, recommended conditions, or other related matters.
  - c) The unplanned release or theft of any transgenic wheat plants or plant parts.

OR120018\_BR\_010819



MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

December 16, 2003

Mr. Juan A. Roman  
Team Leader, Permitting and Notifications  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737-1237

Reference: Change in Site Responsible Researcher

Dear Mr. Roman,

I am writing to inform you that there has been a change in the site responsible researcher on the notifications listed below. The site responsible researcher has changed from (b) (6), (b) (7)(C) CBI, to (b) (6), (b) (7)(C) CBI. The new phone number is (b) (6), (b) (7)(C) CBI. The researcher address, (b) (6), (b) (7)(C) HI (b) (6), (b) (7)(C) CBI, remains the same.

<u>USDA</u>	<u>Monsanto #</u>
03-209-03n	2003-414XRAB
03-265-08n	2003-520XRAB

Please feel free to contact me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely yours,

(b) (6), (b) (7)(C)

cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO

OR120018\_BR\_010820



MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

## CBI-DELETED

December 16, 2003

Mr. Juan A. Roman  
Team Leader, Permitting and Notifications  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737-1237

Reference: Change in Site Responsible Researcher

Dear Mr. Roman,

I am writing to inform you that there has been a change in the site responsible researcher on the notifications listed below. The site responsible researcher has changed from [CBI DELETED] – CBI, to [CBI DELETED] - CBI. The new phone number is [CBI DELETED] – CBI. The researcher address, [CBI DELETED] – CBI, remains the same.

<u>USDA</u>	<u>Monsanto #</u>
03-209-03n	2003-414XRAB
03-265-08n	2003-520XRAB

Please feel free to contact me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely yours,

(b) (6), (b) (7)(C)

cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO

OR120018\_BR\_010821



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-209-03n**      **Monsanto #2003-414XRAB**

**December 22, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

Location  
2147316661

County  
Honolulu

State  
HI

Honolulu County/HI (2147316661)

(b)(4)

apl  
12/27/04



(b)(4)



(b)(4)



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-209-03n**      **Monsanto #2003-414XRAB**

**December 22, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147316661	Honolulu	HI

**Honolulu County/HI (2147316661)**

**Planting Date:** 10/27/2003

**Harvest Date:** 03/09/2004

**Destruct Date:** 05/06/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Planting Date:** 12/22/2003

**Harvest Date:** 04/16/2004

**Destruct Date:** 05/06/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



9/26/03 1:19 pm

## Notification Tracking Sheet

Bp number: 03-258-16n

App number: 2003-506XRAB  
 Received: 9/15/03  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 10/15/03  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: **(b) (6), (b) (7)(C)**  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway North  
 Address3:  
 Address4:  
 City/State/Zip: St. Louis, MO 63198  
 Telephone: **(b) (6), (b) (7)(C)**  
 Begin movement: 10/12/03  
 End movement: 10/12/04  
 Begin release: 10/12/03  
 End release: 10/12/04  
 Acre: 20.00  
 CBI status: CBI  
 Fax: 636-737-7085

- |  | Initial         | Date         |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]  | [ 9/29/03 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>Jmc</i> ]* | [ 9/29/03 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLD</i> ]  | [ 9/30/03 ]* |
| 4. <input type="checkbox"/> State response   |                 |              |

O/d	Loc	Site	Reg			
Interstate	*Dest*AZ	*	*WR	*	[	]
Interstate	*Dest*CA	*	*WR	*	[	]
Interstate	*Dest*MN	*	*NER	*	[	]
Interstate	*Dest*MO	*	*SCR	*	[	]
Interstate	*Dest*MT	*	*WR	*	[	]
Interstate	*Dest*ND	*	*SCR	*	[	]
Interstate	*Orig*AZ	*	*WR	*	[	]
Interstate	*Orig*CA	*	*WR	*	[	]
Interstate	*Orig*MN	*	*NER	*	[	]
Interstate	*Orig*MO	*	*SCR	*	[	]
Interstate	*Orig*MT	*	*WR	*	[	]
Interstate	*Orig*ND	*	*SCR	*	[	]
Release	*	*CA	*	1*WR	*	[

- |  |                |               |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajd</i> ] | [ 9/29/03 ]   |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KLD</i> ] | [ 10/23/03 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KLD</i> ] | [ 10/24/03 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify |                |               |



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imagine  
CONFIDENTIAL



MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-506XRAB

Permit Unit

September 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-258-16n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-506XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

October 12, 2003 - October 12, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** HJ - 98, Oakley, NS Expt lines, WPB Expt. lines



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-506XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-506XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/15	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

150,000 pounds Ship up to 150,000 pounds of wheat seed to and from each location.

### ORIGIN:

AZ, CA, MN, MO, MT, ND

### DESTINATION:

AZ, CA, MN, MO, MT, ND

### Ship From/Ship To:

AZ

\* (b) (4) Yuma County/Province, AZ, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

CA

\* (b) (4) Imperial County/Province, CA, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

\* (b) (4), (b) (6), (b) (7)(C) Imperial County/Province, CA, (b) (4), (b) (6), (b) (7)(C) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

MN

\* (b) (4) Marshall County/Province, MN, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)



*CONFIDENTIAL*

Monsanto Reference ID  
2003-506XRAB

218/437-6638

] -CBI

\*[ (b) (4) St. Paul, Ramsey County/Province,  
MN, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
MN, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] -CBI

MO

\*[ (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MT

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

ND

\*[ (b) (4) Cass  
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-506XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA(1)

CA

(b) (4), (b) (6), (b) (7)(C) Imperial County/Province, CA, (b) (4), (b) (6), (b) (7)(C) USA, 20 acres.

**RESPONSIBLE PERSON/RESEARCHER:**

(b) (4), (b) (6), (b) (7)(C)

CA

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

J-CBI





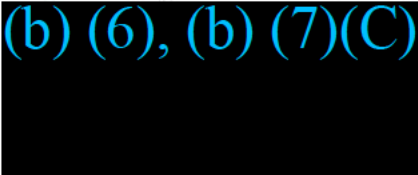
**Monsanto Reference ID**  
2003-506XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 12, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO  
imagine  
CBI-DELETED



MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-506XRAB

Permit Unit

September 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-258-16n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-506XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

October 12, 2003 - October 12, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): HJ - 98, Oakley, NS Expt lines, WPB Expt. lines



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

150,000 pounds. Ship up to 150,000 pounds of wheat seed to and from each location.

#### **ORIGIN:**

AZ, CA, MN, MO, MT, ND

#### **DESTINATION:**

AZ, CA, MN, MO, MT, ND

#### **Ship From/Ship To:**

##### **AZ**

[ CBI Deleted ] -- \*Yuma County/Province, AZ, USA

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **MN**

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

##### **ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA(1)

**CA**

[ CBI Deleted ] -- Imperial County/Province, CA, USA, 20 acres.





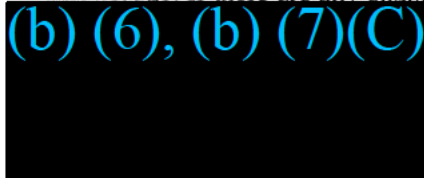
**Monsanto Reference ID**  
2003-506XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 12, 2003



MONSANTO  
imagine  
CBI-DELETED



MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-506XRAB

Permit Unit

September 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-258-16n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-506XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

October 12, 2003 - October 12, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): HJ - 98, Oakley, NS Expt lines, WPB Expt. lines



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

150,000 pounds. Ship up to 150,000 pounds of wheat seed to and from each location.

#### **ORIGIN:**

AZ, CA, MN, MO, MT, ND

#### **DESTINATION:**

AZ, CA, MN, MO, MT, ND

#### **Ship From/Ship To:**

##### **AZ**

[ CBI Deleted ] -- \*Yuma County/Province, AZ, USA

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **MN**

[ CBI Deleted ] -- \*Marshall County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

##### **ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-506XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA(1)

CA

[ CBI Deleted ] -- Imperial County/Province, CA, USA, 20 acres.



MONSANTO  
imagine  
*CBI-DELETED*



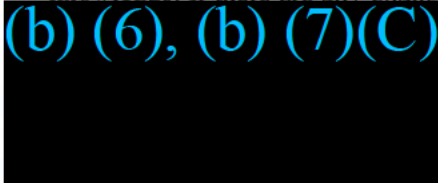
**Monsanto Reference ID**  
2003-506XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 12, 2003



file copy

Mr. David Madison  
Arizona Department of Agriculture  
1688 West Adams St.  
Phoenix, AZ 85007

September 26, 2003

Dear Mr. Madison:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

191

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010849



file copy

Re-sent 10/23/03

6 pages

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 26, 2003

Dear Mr. Brown:

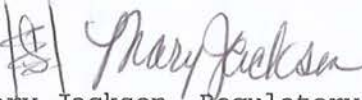
Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010850



file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

September 26, 2003

Dear Dr. Hanks:


Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010851





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 26, 2003

Dear Mr. Brown:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010852



file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

September 26, 2003

Dear Ms. Witham:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-258-16n	Applicant #:	2003-506XRAB
Received:	September 15, 2003	Effective:	October 15, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MN MO MT ND		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010853



file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

September 26, 2003

Dear Mr. Nelson:


Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010854





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David Madison  
Arizona Department of Agriculture  
1688 West Adams St.  
Phoenix, AZ 85007

September 26, 2003

Dear Mr. Madison:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 10/14/03

State: Arizona

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010855

OCT 14 2003

TOTAL P.08



Oct-23-03 02:44pm From-

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file copy

6 pages

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 26, 2003

Dear Mr. Brown:


Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

 (b) (6), (b) (7)(C)  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

## STATE RESPONSE TO NOTIFICATION

  X   State concurs with APHIS determination.; provided, all applicable quarantine requirements are met (see attached).

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S Brown (916) 654-1017Signature: (b) (6), (b) (7)(C)Date: October 23, 2003State: California

Rptloc01/R4





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

September 26, 2003

Dear Dr. Hanks:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *movement only*

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 10-7-03

State: MN

Rptloc01/R4



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OCT 7 2003





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

September 26, 2003

Dear Ms. Witham:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-258-16n	Applicant #:	2003-506XRAB
Received:	September 15, 2003	Effective:	October 15, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MN MO MT ND		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Lori Witham

Signature

(b) (6), (b) (7)(C)

Date:

10/1/03

State:

Montana

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020



Dear Mr. Nelson:

Enclosed is notification 03-258-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-258-16n Applicant #: 2003-506XRAB  
Received: September 15, 2003 Effective: October 15, 2003  
Institution: Monsanto Recipient: Wheat  
Interstate destination: AZ CA MN MO MT ND  
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: D. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 10/12/03

State: ND

Rptloc01/R4



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OR120018\_BR\_010859

OCT 14 2003

OCT.12.2003 4:20PM

NOV.06.2003 4:20PM



October 23, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 23, 2003.

**Interstate movement and Release**

**Notification no. 03-258-16n (2003-506XRAB)**

**Regulated article - Wheat**

**Destinations - Arizona, California, Minnesota, Missouri, Montana, North Dakota**

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The state of Minnesota concurs with APHIS determination for movement only.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

/s/

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

OR120018\_BR\_010860



cc:

D. Madison, Arizona Dept. of Agric., Phoenix, AZ  
S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
File number 03-258-16n



**California Quarantine Requirements**  
**USDA/APHIS Biotechnology Notification No. 03-258-16N**

1. Shipments of wheat seed to California from parts of Montana and North Dakota shall meet the requirements of Title 3, California Code of Regulations, Section 3277, Cereal Leaf Beetle Exterior Quarantine.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 339-4314.



# Confirmation Report-Memory Send

Time : Oct-24-03 10:18am  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 787  
Date : Oct-24 10:17am  
To : 916367377085  
Document Pages : 03  
Start time : Oct-24 10:17am  
End time : Oct-24 10:18am  
Pages sent : 03  
Job number : 787

\*\*\* SEND SUCCESSFUL \*\*\*



Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

October 23, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 23, 2003.

Interstate movement and Release  
Notification no. 03-258-16n (2003-506XRAB)

Regulated article - Wheat

Destinations - Arizona, California, Minnesota, Missouri, Montana, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3 (c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The state of Minnesota concurs with APHIS determination for movement only.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure



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An Equal Opportunity Employer

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MONSANTO



**NO CBI**

**MONSANTO COMPANY**

800 NORTH LINDBERGH BOULEVARD  
ST. LOUIS, MISSOURI 63167  
PHONE (314) 694-1000  
<http://www.monsanto.com>

March 9, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

**USDA**

**Monsanto#**

03-258-16n	2003-506XRAB
04-009-03n	2004-6XRAB
04-015-12n	2004-35XRAB
04-034-08n	2004-194XRAB
04-035-06n	2004-225XRAB
04-056-09n	2004-336XRAB
04-064-07n	2004-375XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

apl  
3/11/05

OR120018\_BR\_010864



*CONFIDENTIAL*

**2003 Wheat Field Test Report**  
**USDA #03-258-16n** **Monsanto #2003-506XRAB**

**March 9, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

**Location**

2147318582

**County**

Imperial

**State**

CA

**Imperial County/CA (2147318582)**

(b) (4)

*mm*  
*3/9/05*



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



**NO CBI**

**MONSANTO COMPANY**

800 NORTH LINDBERGH BOULEVARD

ST. LOUIS, MISSOURI 63167

PHONE (314) 694-1000

<http://www.monsanto.com>

March 9, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

**USDA**

**Monsanto#**

03-258-16n	2003-506XRAB
04-009-03n	2004-6XRAB
04-015-12n	2004-35XRAB
04-034-08n	2004-194XRAB
04-035-06n	2004-225XRAB
04-056-09n	2004-336XRAB
04-064-07n	2004-375XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

apl  
3/11/05



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-258-16n**      **Monsanto #2003-506XRAB**

**March 9, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147318582	Imperial	CA

**Imperial County/CA (2147318582)**

**Planting Date:** 11/14/2003

**Harvest Date:** 05/14/2004

**Destruct Date:** 05/24/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

3/11/05



=====  
 Bp number: 03-283-02n  
 =====

App number: 2003-544XRAB      Begin movement: 11/08/03  
 Received: 10/10/03      End movement: 11/08/04  
 Institution: Monsanto      Begin release: 11/08/03  
 Recipient: Wheat      End release: 11/08/04  
 Status: Pending      Acre: 4.00  
 Effective date: 11/09/03      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway North  
 Address3:  
 Address4:  
 City/State/Zip: St. Louis, MO 63198  
 Telephone: (b) (6), (b) (7)(C)      Fax: 636-737-7085

- |  | Initial         | Date           |
|--|-----------------|----------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]  | [ 10/16/03 ]   |
| 2. <input type="checkbox"/> Review by biotechnologist                                | [ <i>VM</i> ] * | [ 10/16/03 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLO</i> ]  | [ 10/21/03 ] * |
| 4. <input type="checkbox"/> State response   |                 |                |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CA	*	*WR	*	[ ] [ ]
Interstate	*Dest*	MO	*	*SCR	*	[ ] [ ]
Interstate	*Orig*	CA	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	CA	*	2*WR	*	[ ] [ ]

- |  |                |                |
|--|----------------|----------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajd</i> ] | [ 10/16/03 ]   |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KLO</i> ] | [ 10/27/03 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KLO</i> ] | [ 10/28/03 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |                |



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



REDACTED



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-544XRAB

Permit Unit

October 9, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

**1. USDA Reference Number** 03-283-02n

**2. Application Reference Number** 2003-544XRAB

**3. Application/Responsible Party**

(b) (7)(C), (b) (6)

Phone (b) (6), (b) (7)

Fax 636/737-7085

Email (b) (6), (b) (7) @monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release November 8, 2003 - November 8, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction**      Interstate Movement and Release

A total of 7000 pounds of wheat seed may be shipped for the duration of this notification. Ship up to 3000 pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, MO

#### **DESTINATION:**

CA, MO

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

[ CBI Deleted ] -- \*Fresno County/Province, CA, USA

[ CBI Deleted ] -- \*Placer County/Province, CA, U.S.A.

[ CBI Deleted ] -- \*Yolo County/Province, CA, U.S.A.

[ CBI Deleted ] -- \*Madera County/Province, CA, USA

[ CBI Deleted ] -- \*Fresno County/Province, CA, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.



*CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA(2)

CA

[ CBI Deleted ] -- Yolo County/Province, CA, U.S.A., 2 acres.

[ CBI Deleted ] -- Fresno County/Province, CA, U.S.A., 2 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

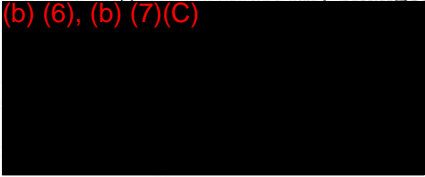
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 9, 2003



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**

2003-544XRAB

Permit Unit

October 9, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-283-02n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-544XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Monsanto Company

Email

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

November 8, 2003 - November 8, 2004

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction**      Interstate Movement and Release

A total of 7000 pounds of wheat seed may be shipped for the duration of this notification. Ship up to 3000 pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, MO

#### **DESTINATION:**

CA, MO

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA  
[ CBI Deleted ] -- \*Fresno County/Province, CA, USA  
[ CBI Deleted ] -- \*Placer County/Province, CA, U.S.A.  
[ CBI Deleted ] -- \*Yolo County/Province, CA, U.S.A.  
[ CBI Deleted ] -- \*Madera County/Province, CA, USA  
[ CBI Deleted ] -- \*Fresno County/Province, CA, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.



*CBI-DELETED*

**Monsanto Reference ID**  
2003-544XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA(2)

**CA**

[ CBI Deleted ] -- Yolo County/Province, CA, U.S.A., 2 acres.

[ CBI Deleted ] -- Fresno County/Province, CA, U.S.A., 2 acres.



MONSANTO



*CBI-DELETED*

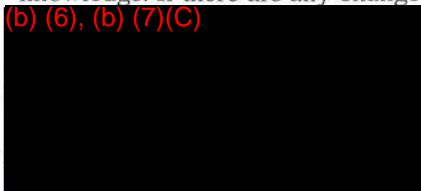
**Monsanto Reference ID**  
2003-544XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 9, 2003



file copy

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

October 16, 2003

Dear Mr. Brown:

Enclosed is notification 03-283-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-283-02n	Applicant #:	2003-544XRAB
Received:	October 10, 2003	Effective:	November 9, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010891





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

October 16, 2003

Dear Mr. Brown:

Enclosed is notification 03-283-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-283-02n	Applicant #:	2003-544XRAB
Received:	October 10, 2003	Effective:	November 9, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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OR120018\_BR\_010892





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

October 16, 2003

Dear Mr. Brown:

Enclosed is notification 03-283-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-283-02n	Applicant #:	2003-544XRAB
Received:	October 10, 2003	Effective:	November 9, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature: \_\_\_\_\_

Date: October 23, 2003

State: California

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OCT 23 2003

OR120018\_BR\_010893



October 27, 2003

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after November 9, 2003.

Interstate movement and Release  
Notification no. 03-283-02n (2003-544XRAB)  
Regulated article - Wheat  
Destinations - California, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 03-283-02n

OR120018\_BR\_010894



California Quarantine Requirements  
USDA/APIIS Biotechnology Notification No. 03-283-02N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.
3. Permittee shall notify the Office of the Fresno County Agricultural Commissioner upon arrival of Shipments (559) 456-7379.
4. Permittee shall notify the Office of the Placer County Agricultural Commissioner upon arrival of Shipments (530) 823-1698.
5. Permittee shall notify the Office of the Yolo County Agricultural Commissioner upon arrival of Shipments (530) 662-6094.
6. Permittee shall notify the Office of the Madera County Agricultural Commissioner upon arrival of Shipments (559) 674-4071.



# Confirmation Report-Memory Send

Time : Oct-28-03 10:54am  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 827  
Date : Oct-28 10:53am  
To : 916367377085  
Document Pages : 04  
Start time : Oct-28 10:53am  
End time : Oct-28 10:54am  
Pages sent : 04  
Job number : 827

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

October 27, 2003

(b) (6), (b) (7)(C)

Memphis Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after November 9, 2003.

Interstate movement and Release  
Notification no. 03-283-02n (2003-544KRAB)  
Regulated article - Wheat  
Destinations - California, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010896



REDACTED



REDACTED



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



by tillage.] - CBI



*CBI-DELETED*

**2003 Wheat Field Test Report**

**USDA #03-283-02n**

**Monsanto #2003-544XRAB**

**February 16, 2005**

**Biotech Field Compliance Team  
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
1600490622	Yolo	CA
8052	Fresno	CA

**Yolo County/CA (1600490622)**

**Planting Date:** 12/18/2003

**Harvest Date:** 06/11/2004

**Destruct Date:** 07/17/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Fresno County/CA (8052)**

**Planting Date:** 01/16/2004

**Harvest Date:** 06/09/2004



**Destruct Date:** 06/14/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]



12/23/03 1:05 pm

Notification Tracking Sheet

=====

Bp number: 03-357-01n

=====

App number: 2003-648XRAB  
Received: 12/23/03  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 1/22/04  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 1/21/04  
End movement: 1/21/05  
Begin release: 1/21/04  
End release: 1/21/05  
Acre: 20.00  
CBI status: CBI  
Fax: 636-737-7085

- =====
- |  | Initial          | Date           |
|--|------------------|----------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ayd</i> ]   | [ 12/23/03 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>gmc</i> ] * | [ 12/29/03 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLO</i> ]   | [ 1/5/04 ] *   |
| 4. <input type="checkbox"/> State response   |                  |                |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*	[ ]
Interstate	*Dest*	WA	*	*WR	*	[ ]
Interstate	*Orig*	MO	*	*SCR	*	[ ]
Interstate	*Orig*	WA	*	*WR	*	[ ]
Release	*	WA	*	1*WR	*	[ ]

- |  |                |               |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ayd</i> ] | [ 12/29/03 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KLO</i> ] | [ 1/20/04 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KLO</i> ] | [ 1/21/04 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |               |



MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-648XRAB

Permit Unit

December 22, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-357-01n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-648XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release January 21, 2004 - January 21, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2003-648XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2003-648XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

20,000 pounds. Ship up to 20,000 pounds of wheat seed to/from each location.

### ORIGIN:

MO, WA

### DESTINATION:

MO, WA

### Ship From/Ship To:

MO

\* [REDACTED] (b) (4) St. Louis County/Province,  
MO (b) (4) USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MO (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED]

] -CBI

\* [REDACTED] (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MO, (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED]

] -CBI

\* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)  
U.S.A.

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)  
U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* [REDACTED] (b) (4) St. Louis County County/Province, MO (b) (4)  
USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-648XRAB

(b) (4), (b) (5), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

WA

\* (b) (4) Grant County/Province, WA (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C), WA (b) (4), (b) (6), (b) (7)(C)

J-CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-648XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

WA

(b) (4) Grant County/Province, WA, (b) (4) USA, 20  
acres. (519)

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] -CBI



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*CONFIDENTIAL*

**Monsanto Reference ID**  
2003-648XRAB

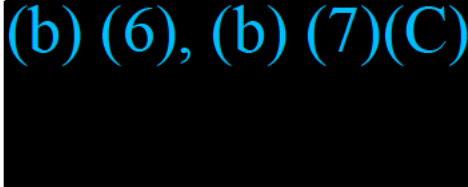
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

December 22, 2003



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-648XRAB

Permit Unit

December 22, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-357-01n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-648XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

January 21, 2004 - January 21, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

### **Monsanto Reference ID**

2003-648XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 pounds. Ship up to 20,000 pounds of wheat seed to/from each location.

#### **ORIGIN:**

MO, WA

#### **DESTINATION:**

MO, WA

#### **Ship From/Ship To:**

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.

[ CBI Deleted ] -- \*St. Louis County County/Province, MO, USA

##### **WA**

[ CBI Deleted ] -- \*Grant County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

**WA**

[ CBI Deleted ] -- Grant County/Province, WA, USA, 20 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

December 22, 2003



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**  
2003-648XRAB

Permit Unit

December 22, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-357-01n

**1. USDA Reference Number**

**2. Application Reference Number** 2003-648XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

January 21, 2004 - January 21, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

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Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 pounds. Ship up to 20,000 pounds of wheat seed to/from each location.

#### **ORIGIN:**

MO, WA

#### **DESTINATION:**

MO, WA

#### **Ship From/Ship To:**

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

[ CBI Deleted ] -- \*St. Louis County/Province, MO, U.S.A.

[ CBI Deleted ] -- \*St. Louis County County/Province, MO, USA

##### **WA**

[ CBI Deleted ] -- \*Grant County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2003-648XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

WA

[ CBI Deleted ] -- Grant County/Province, WA, USA, 20 acres.



MONSANTO



*CBI-DELETED*

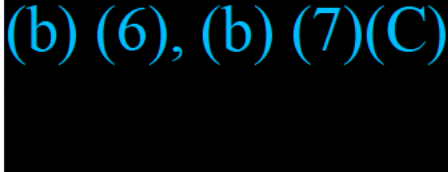
**Monsanto Reference ID**  
2003-648XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria **and** the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

December 22, 2003



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

December 23, 2003

Dear Mr. Brown:

Enclosed is notification 03-357-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-357-01n	Applicant #:	2003-648XRAB
Received:	December 23, 2003	Effective:	January 22, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010924



file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

December 23, 2003

Dear Mr. Wessels:

Enclosed is notification 03-357-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-357-01n	Applicant #:	2003-648XRAB
Received:	December 23, 2003	Effective:	January 22, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010925





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

December 23, 2003

Dear Mr. Wessels:

Enclosed is notification 03-357-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-357-01n	Applicant #:	2003-648XRAB
Received:	December 23, 2003	Effective:	January 22, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/13/04

State: WA

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_010926

JAN 13 2004



January 20, 2004

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after January 22, 2004.

Interstate movement and Release  
Notification no. 03-357-01n (2003-648XRAB)  
Regulated article - Wheat  
Destinations - Missouri, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 03-357-01n

OR120018\_BR\_010927



## Confirmation Report-Memory Send

Time : Jan-20-04 01:43pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 630  
Date : Jan-20 01:42pm  
To : 916367377085  
Document Pages : 03  
Start time : Jan-20 01:42pm  
End time : Jan-20 01:43pm  
Pages sent : 03  
Job number : 630

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

January 20, 2004

(b) (6), (b) (7)(C)

Monasisco Company  
700 Chesterfield Parkway W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after January 22, 2004.

Interstate movement and Release  
Notification no. 03-357-01n (2003-648XRAB)  
Regulated article - Wheat  
Destinations - Missouri, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
T. Wessels, Washington Dept. of Agric., Olympia, WA



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An Equal Opportunity Employer

OR120018\_BR\_010928



MONSANTO



MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

NO CBI

April 25, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

<u>USDA</u>	<u>Monsanto#</u>
03-357-01n	2003-648XRAB
04-015-09n	2004-32XRAB
04-035-02n	2004-110XRAB
04-057-03n	2004-184XRAB
04-076-10n	2004-417XRAB
04-085-12n	2004-419XRAB
04-090-02n	2004-346XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

OR120018\_BR\_010929

ajal  
4/26/05



*CONFIDENTIAL*

**2003 Wheat Field Test Report**

**USDA #03-357-01n**

**Monsanto #2003-648XRAB**

**April 25, 2005**

**Biotech Field Compliance Team  
Monsanto Company**

Location

519

County

Grant

State

WA

Grant County/WA (519)

(b) (4)



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

NO CBI

April 25, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

<u>USDA</u>	<u>Monsanto#</u>
03-357-01n	2003-648XRAB
04-015-09n	2004-32XRAB
04-035-02n	2004-110XRAB
04-057-03n	2004-184XRAB
04-076-10n	2004-417XRAB
04-085-12n	2004-419XRAB
04-090-02n	2004-346XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

OR120018\_BR\_010934

ajal  
4/26/05



*CBI-DELETED*

**2003 Wheat Field Test Report**  
**USDA #03-357-01n                      Monsanto #2003-648XRAB**

**April 25, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
519	Grant	WA

**Grant County/WA (519)**

**Planting Date:** 04/15/2004

**Destruct Date:** 06/14/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



1/21/04 2:37 pm

Notification Tracking Sheet

=====  
Bp number: 04-009-03n  
=====

App number: 2004-6XRAB  
Received: 1/09/04  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 2/08/04  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person:  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: (b) (6), (b) (7)(C)  
Begin movement: 2/07/04  
End movement: 2/07/05  
Begin release: 2/07/04  
End release: 2/07/05  
Acre:  
CBI status: CBI

=====  
Fax: 636-737-7085  
=====

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[aid]	[1/22/04]
2. [✓] Review by biotechnologist	[mw]	[1/22/04]*
3. [✓] Letter of notification to State <i>Fed-ex</i>	[KLR]	[1/28/04]*
4. [ ] State response		

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Interstate	*Orig*WA	*	*WR *
Release	* *ID	*	1*WR *
Release	* *MT	*	4*WR *
Release	* *WA	*	3*WR *

5. [✓] Enter genes into database	[aid]	[1/22/04]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[KLR]	[3/25/04]*
7. [✓] Enter final data into database	[KLR]	[4/6/04]
8. [ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		



MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-6XRAB

Permit Unit

January 8, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-009-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-6XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release February 7, 2004 - February 7, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2004-6XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
2004-6XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

20,000 lbs Ship up to \_20,000\_pounds wheat seed to and from each location.

### ORIGIN:

HI, ID, MO, MT, WA

### DESTINATION:

HI, ID, MO, MT, WA

### Ship From/Ship To:

#### HI

\*[REDACTED] (b) (4) Honolulu  
County/Province, (b) (4) HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A.

J-CBI

#### ID

\*[REDACTED] (b) (4)  
(b) (4) Bingham County/Province, ID, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)

J-CBI

#### MO

\*[REDACTED] (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA

J-CBI



CONFIDENTIAL

Monsanto Reference ID  
2004-6XRAB

MT

\* (b) (4) Fergus County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* [(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4), (b) (6), (b) (7)(C) Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* [(b) (4) Park County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,



CONFIDENTIAL

Monsanto Reference ID  
2004-6XRAB

(b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

\* (b) (4) (b) (4) Adams County/Province, WA,  
(b) (4) Adams

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Whitman County/Province, WA, (b) (4)  
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Whitman  
County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Lincoln County/Province, WA,  
(b) (4) Lincoln

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

Monsanto Reference ID  
2004-6XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1), MT(4), WA(3)

**ID**

(b) (4) Bingham County/Province, ID (b) (4) U.S.A., 6 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)

J-CBI

**MT**

(b) (4) Fergus County/Province, MT, (b) (4) USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 4 acres.  
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Gallatin County/Province, MT, (b) (4) USA, 6 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-6XRAB

]CBI

WA

[ (b) (4) Adams County/Province, WA,  
(b) (4) Adams, 4 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]CBI

(b) (4) Whitman County/Province, WA, (b) (4)  
USA, 6 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]CBI

(b) (4), (b) (6), (b) (7)(C) Lincoln County/Province, WA, (b) (4), (b) (6), (b) (7)(C)  
Lincoln, 4 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-6XRAB

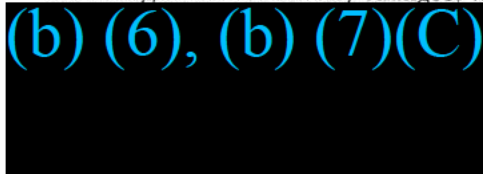
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 8, 2004



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-6XRAB

Permit Unit

January 8, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-009-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-6XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release February 7, 2004 - February 7, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 lbs Ship up to \_20,000\_pounds wheat seed to and from each location.

#### **ORIGIN:**

HI, ID, MO, MT, WA

#### **DESTINATION:**

HI, ID, MO, MT, WA

#### **Ship From/Ship To:**

##### **HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, U.S.A.

##### **ID**

[ CBI Deleted ] -- \*Bingham County/Province, ID, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Park County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

##### **WA**

[ CBI Deleted ] -- \*Adams County/Province, WA, Adams



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln



*CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1), MT(4), WA(3)

**ID**

[ CBI Deleted ] -- Bingham County/Province, ID, U.S.A., 6 acres.

**MT**

[ CBI Deleted ] -- Fergus County/Province, MT, USA, 4 acres.

[ CBI Deleted ] -- Teton County/Province, MT, USA, 4 acres.

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 6 acres.

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 10 acres.

**WA**

[ CBI Deleted ] -- Adams County/Province, WA, Adams, 4 acres.

[ CBI Deleted ] -- Whitman County/Province, WA, USA, 6 acres.

[ CBI Deleted ] -- Lincoln County/Province, WA, Lincoln, 4 acres.



MONSANTO



*CBI-DELETED*

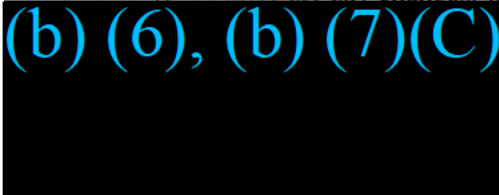
**Monsanto Reference ID**  
2004-6XRAB

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 8, 2004



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-6XRAB

Permit Unit

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USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-009-03n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-6XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 7, 2004 - February 7, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/15	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

20,000 lbs Ship up to \_20,000\_pounds wheat seed to and from each location.

#### **ORIGIN:**

HI, ID, MO, MT, WA

#### **DESTINATION:**

HI, ID, MO, MT, WA

#### **Ship From/Ship To:**

##### **HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, U.S.A.

##### **ID**

[ CBI Deleted ] -- \*Bingham County/Province, ID, U.S.A.

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Park County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

##### **WA**

[ CBI Deleted ] -- \*Adams County/Province, WA, Adams



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-6XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1), MT(4), WA(3)

**ID**

[ CBI Deleted ] -- Bingham County/Province, ID, U.S.A., 6 acres.

**MT**

[ CBI Deleted ] -- Fergus County/Province, MT, USA, 4 acres.

[ CBI Deleted ] -- Teton County/Province, MT, USA, 4 acres.

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 6 acres.

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 10 acres.

**WA**

[ CBI Deleted ] -- Adams County/Province, WA, Adams, 4 acres.

[ CBI Deleted ] -- Whitman County/Province, WA, USA, 6 acres.

[ CBI Deleted ] -- Lincoln County/Province, WA, Lincoln, 4 acres.



MONSANTO



*CBI-DELETED*

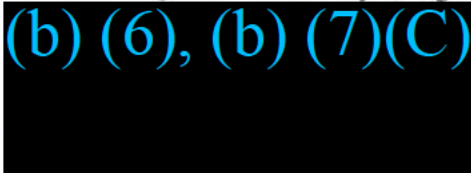
**Monsanto Reference ID**  
2004-6XRAB

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CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 8, 2004



file copy

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

January 21, 2004

Dear Mr. Cooper:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010960



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010961



file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:


Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010962



file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

January 21, 2004

Dear Mr. Wessels:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_010963





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Neil Reimer, Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
1849 Auiki Street  
Honolulu, HI 96819-3100

January 21, 2004

Dear Dr. Reimer:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

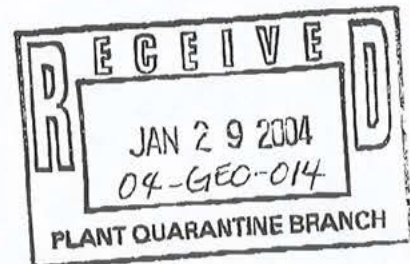
Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO



STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, HI 96819.  
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 24 March 2004

State: Hawaii

Rptloc01/R4

\*The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.



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OR120018\_BR\_010964

999-F-20/02 P 060 T-460

8908288884

03-24-04 09:53pm From-PLANT QUARANTINE HNL

MAR 24 2004





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

January 21, 2004

RECEIVED

JAN 29 2004

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Cooper

Signature

(b) (6), (b) (7)(C)

Date: 1/30/04

State: Idaho

Rptloc01/R4



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FEB 2 2004





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-009-03n Applicant #: 2004-6XRAB  
Received: January 9, 2004 Effective: February 8, 2004  
Institution: Monsanto Recipient: Wheat  
Interstate destination: HI ID MO MT WA  
Release destination: ID MT WA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date: 2/2/04

State: Montana

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

January 21, 2004

Dear Mr. Wessels:

Enclosed is notification 04-009-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-009-03n	Applicant #:	2004-6XRAB
Received:	January 9, 2004	Effective:	February 8, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID MO MT WA		
Release destination:	ID MT WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/3/04

State: WA

Rptloc01/R4



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FEB 3 2004



March 25, 2004

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 25, 2004.

**Interstate movement and Release**

Notification no. 04-009-03n (2004-6XRAB)

Regulated article - Wheat

Destinations - Hawaii, Idaho, Missouri, Montana, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Ms. Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii  
Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii  
96819, upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

JS

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

OR120018\_BR\_010968



cc:

N. Reimer, Hawaii Dept. of Agric., Honolulu, HI  
M. Cooper, Idaho State Dept. of Agric., Boise, ID  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 04-009-03n



# Confirmation Report-Memory Send

Time : Apr-05-04 05:18pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 141  
Date : Apr-05 05:17pm  
To : 916367377085  
Document Pages : 04  
Start time : Apr-05 05:17pm  
End time : Apr-05 05:18pm  
Pages sent : 04  
Job number : 141

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

March 25, 2004

(b) (6), (b) (7)(C)

Memphis Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 25, 2004.

Interstate movement and Release  
Notification no. 04-009-03n (2004-6XRAB)  
Regulated article - Wheat  
Destinations - Hawaii, Idaho, Missouri, Montana, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The movement of wheat seed into Hawaii is unrestricted. Wheat planters and green tissue require state permits. Please call Ms. Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Katy Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure



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An Equal Opportunity Employer

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**CONFIDENTIAL**

**2004 Wheat Field Test Report**

**USDA #04-009-03n**

**Monsanto #2004-6XRAB**

**March 9, 2005**

**Biotech Field Compliance Team  
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317548	Bingham	ID	Not Planted
2147315700	Fergus	MT	
2147315696	Teton	MT	
2147316016	Gallatin	MT	
2147308221	Gallatin	MT	Not Planted
2147314278	Adams	WA	Not Planted
2147306763	Whitman	WA	
2147317254	Lincoln	WA	Not Planted

**Fergus County/MT (2147315700)**

(b)(4)

*mm  
3/11/05*



(b)(4)

Teton County/MT (2147315696)

(b)(4)

Gallatin County/MT (2147316016)

(b)(4)



(b)(4)

Whitman County/WA (2147306763)

(b)(4)



(b)(4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



**CBI-DELETED**

**2004 Wheat Field Test Report**  
**USDA #04-009-03n**      **Monsanto #2004-6XRAB**

**March 9, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317548	Bingham	ID	Not Planted
2147315700	Fergus	MT	
2147315696	Teton	MT	
2147316016	Gallatin	MT	
2147308221	Gallatin	MT	Not Planted
2147314278	Adams	WA	Not Planted
2147306763	Whitman	WA	
2147317254	Lincoln	WA	Not Planted

**Fergus County/MT (2147315700)**

**Planting Date:** 04/13/2004

**Destruct Date:** 05/15/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Teton County/MT (2147315696)**

**Planting Date:** 04/12/2004

3/10/05



**Destruct Date:** 06/12/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Gallatin County/MT (2147316016)**

**Planting Date:** 04/14/2004

**Destruct Date:** 06/08/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Whitman County/WA (2147306763)**

**Planting Date:** 04/07/2004

**Harvest Date:** 09/08/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]



**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]



MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notification(s):

<u>USDA#</u>	<u>Monsanto#</u>
04-009-03n	2004-6XRAB

The former name/address information is:

(b)(4)  
(b)(4) Bingham, ID, (b)(4) - CBI

The new name/address information is:

I (b)(4) Bingham,  
ID, (b)(4) - CBI

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

cc:

Ralph Stoaks

OR120018\_BR\_010980



MONSANTO



**CBI-DELETED**

MONSANTO COMPANY

700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notification(s):

USDA#

04-009-03n

Monsanto#

2004-6XRAB

The former name/address information is:

[ CBI Deleted ] - Bingham, ID

The new name/address information is:

[ CBI Deleted ] - Bingham, ID

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

cc:

Ralph Stoaks

OR120018\_BR\_010981



# NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

AHPIS Notification Number: 04-009-0316 Crop: Wheat (Round Ready hard spring)  
 Applicant's Name: Monsanto Trait/Gene: Glyphosate tolerant  
 Name of Company & Cooperator at site: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)  
 Location of site: (b) (6), (b) (7)(C), (b) (4) Date: 6/25/04  
 Type of location: ☒ Farm ☐ Nursery ☐ Other (describe) \_\_\_\_\_  
 GPS/ GIS Coordinates (if available): Latitude \_\_\_\_\_ Longitude \_\_\_\_\_

Provide the answers below. Check "Y" for Yes and "N" for No. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

## I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identity (seed storage, planting & harvest site, borders, field cages, etc.)?

Y ☒ N ☐

B. Was a site map obtained or drawn by your for reference later (For harvest, flower removal, volunteers, etc.)?

Y ☒ N ☐

## II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop?

Y ☒ N ☐

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants?

Y ☒ N ☐

C. Which of the five containment options is the applicant using? Check one of the options below. If none, please note it here and state this in your cover letter to the Regional Program Manager. \_\_\_\_\_

1. Removing Flowers \_\_\_\_\_

Is there any evidence that the plants have flowers or that flowers have been removed?

Y ☐ N ☐

2. Bagging Flowers/Tassels \_\_\_\_\_

Does the applicant have material to bag reproductive structures?

Y ☐ N ☐

3. Terminating the experiment before flowering \_\_\_\_\_

Were plants destroyed or removed from the field before any flowers were allowed to release pollen?

Y ☐ N ☐

4. Physical Isolation \_\_\_\_\_

If there are any non-transgenic compatible plants within the distance stated in Table 1 (for pollination distance), were they being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenic?

Y ☒ N ☐

5. Temporal Isolation \_\_\_\_\_

Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap?

Y ☐ N ☐

ed  
7/6/04



- D. If the applicant's design standards use border rows, are there the stated numbers of border rows? Y ☒ N ☐
- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic? Y ☒ N ☐  
Plants of the same species? Y ☒ N ☐
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y ☒ N ☐
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y ☒ N ☐
- H. Was the field site marked as stated in the design standards? Y ☒ N ☐
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y ☒ N ☐
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y ☒ N ☐

### III. Devitalization

- A. Does the applicant have the necessary equipment to devitalize the plant material as described? Y ☒ N ☐  
In the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y ☒ N ☐
- B. Remind applicant that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed and approved.

The signed original of this report was furnished to Juan Roman, APHIS, RRS. Y ☒ N ☐

Inspecting Officer Signature: (b) (6), (b) (7)(C)

Printed Name: George Bruno

Phone: (509) 353-2950

Location of PPQ Officer: SPOKANE, WASHINGTON

Names and Affiliation of Any Other Persons at the inspection:

(b) (6), (b) (7)(C), (b) (4)

Please fax/ email completed worksheet to:

Ralph Stoaks, Regional Biotechnologist

2150 Centre Ave. Bldg. B, 3E10

Ft. Collins, CO 80526

Phone: 970-494-7573 Fax: 970-494-7576

Email: [ralph.d.stoaks@aphis.usda.gov](mailto:ralph.d.stoaks@aphis.usda.gov)

Please FedEx original worksheet to:

Juan Roman, Chief Biotechnology Program Operations

4700 River Road, Unit 147, 5B53

Riverdale, MD 20737

Phone: 301-734-0029



1/21/04 2:37 pm

Notification Tracking Sheet

=====  
Bp number: 04-015-09n  
=====

App number: 2004-32XRAB  
Received: 1/15/04  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 2/14/04  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Begin movement: 2/13/04  
End movement: 2/13/05  
Begin release: 2/13/04  
End release: 2/13/05  
Acre: 10.00  
CBI status: CBI  
Fax: 636-737-7085

- |  | Initial          | Date          |
|--|------------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajb</i> ]   | [ 1/22/04 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>ymH</i> ] * | [ 1/23/04 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>Kxio</i> ]  | [ 1/29/04 ] * |
| 4. <input type="checkbox"/> State response   |                  |               |

- | O/d        | Loc      | Site | Reg  |   |         |
|------------|----------|------|------|---|---------|
| Interstate | *Dest*CA | *    | *WR  | * | [ ] [ ] |
| Interstate | *Dest*KS | *    | *SCR | * | [ ] [ ] |
| Interstate | *Dest*MO | *    | *SCR | * | [ ] [ ] |
| Interstate | *Dest*MT | *    | *WR  | * | [ ] [ ] |
| Interstate | *Dest*WA | *    | *WR  | * | [ ] [ ] |
| Interstate | *Orig*CA | *    | *WR  | * |         |
| Interstate | *Orig*KS | *    | *SCR | * |         |
| Interstate | *Orig*MO | *    | *SCR | * |         |
| Interstate | *Orig*MT | *    | *WR  | * |         |
| Interstate | *Orig*WA | *    | *WR  | * |         |
| Release    | *WA      | *    | 1*WR | * | [ ] [ ] |
- 
- |  |                 |               |
|--|-----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajb</i> ]  | [ 1/23/04 ]   |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>Kxio</i> ] | [ 2/11/04 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>Kxio</i> ] | [ 2/17/04 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify |                 |               |





CONFIDENTIAL

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-32XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-09n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-32XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2004-32XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

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Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



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**Monsanto Reference ID**  
2004-32XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to \_10,000\_\_pounds of wheat seed to and from each location.

### ORIGIN:

CA, KS, MO, MT, WA

### DESTINATION:

CA, KS, MO, MT, WA

### Ship From/Ship To:

CA

\* (b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

KS

\* (b) (4)  
Riley County/Province, KS (b) (4) JSA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Pottawattamie County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

\* (b) (4), St. Louis County/Province, MO,



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Monsanto Reference ID  
2004-32XRAB

(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA

] -CBI

MT

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

\* (b) (4) Benton County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Walla Walla County/Province,  
WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-32XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

WA

(b) (4)  
WA, (b) (4) USA, 10 acres. (b) (4) Walla Walla County/Province,

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI





*CONFIDENTIAL*

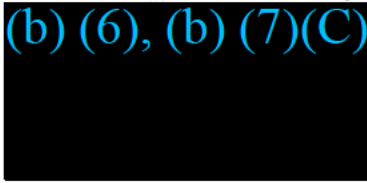
MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-32XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

## Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.





*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-32XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-09n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-32XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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## *CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds. Ship up to \_10,000\_\_pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, KS, MO, MT, WA

#### **DESTINATION:**

CA, KS, MO, MT, WA

#### **Ship From/Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**KS**

[ CBI Deleted ] -- \*Riley County/Province, KS, USA

[ CBI Deleted ] -- \*Pottawattamie County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**WA**

[ CBI Deleted ] -- \*Benton County/Province, WA, USA

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

WA

[ CBI Deleted ] -- Walla Walla County/Province, WA, USA, 10 acres.





*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-32XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004





*CBI-DELETED*

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700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
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700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds. Ship up to \_10,000\_\_pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, KS, MO, MT, WA

#### **DESTINATION:**

CA, KS, MO, MT, WA

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **KS**

[ CBI Deleted ] -- \*Riley County/Province, KS, USA

[ CBI Deleted ] -- \*Pottawattamie County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

##### **WA**

[ CBI Deleted ] -- \*Benton County/Province, WA, USA

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2004-32XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA(1)

WA

[ CBI Deleted ] -- Walla Walla County/Province, WA, USA, 10 acres.





*CBI-DELETED*

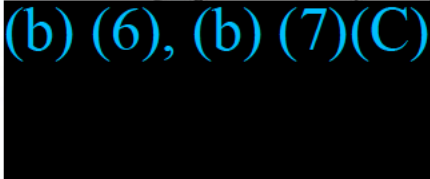
MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-32XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



file copy

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011004



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011005



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011006



file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:


Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011007



file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

January 21, 2004

Dear Mr. Wessels:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011008





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-09n Applicant #: 2004-32XRAB  
Received: January 15, 2004 Effective: February 14, 2004  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CA KS MO MT WA  
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).  
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature:

(b) (6), (b) (7)(C)

Date: February 4, 2004

State: California

Rptloc01/R4





California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 04-015-09N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Kansas, Montana and Washington shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/2/04

State: Montana

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

January 21, 2004

Dear Mr. Wessels:

Enclosed is notification 04-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-09n	Applicant #:	2004-32XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/3/04

State: WA

Rptloc01/R4





February 11, 2004

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2004.

**Interstate movement and Release**

Notification no. 04-015-09n (2004-32XRAB)

Regulated article - Wheat

Destinations - California, Kansas, Missouri, Montana, Washington

**This acknowledgment letter must be provided to all cooperators.**

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 04-015-09n

OR120018\_BR\_011013



California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 04-015-09N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Kansas, Montana and Washington shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.



*CONFIDENTIAL*

**2004 Wheat Field Test Report**  
**USDA #04-015-09n**      **Monsanto #2004-32XRAB**

**April 25, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

Location  
2147312318

County  
Walla Walla

State  
WA

Walla Walla County/WA (2147312318)

(b) (4)



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



***CBI-DELETED***

**2004 Wheat Field Test Report**  
**USDA #04-015-09n                      Monsanto #2004-32XRAB**

**April 25, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147312318	Walla Walla	WA

**Walla Walla County/WA (2147312318)**

**Planting Date:** 03/17/2004

**Destruct Date:** 06/02/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



1/21/04 2:37 pm

Notification Tracking Sheet

=====  
Bp number: 04-015-10n  
=====

App number: 2004-33XRAB  
Received: 1/15/04  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 2/14/04  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: (b) (6), (b) (7)(C)  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: (b) (6), (b) (7)(C)  
Begin movement: 2/13/04  
End movement: 2/13/05  
Begin release: 2/13/04  
End release: 2/13/05  
Acre: 10.00  
CBI status: CBI  
Fax: 636-737-7085  
=====

- |  | Initial           | Date         |
|--|-------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]    | [ 1/22/04 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>shett</i> ]* | [ 1/23/04 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLW</i> ]    | [ 1/29/04 ]* |
| 4. [ ] State response  |                   |              |

- |            | O/d    | Loc | Site | Reg  |   |         |
|------------|--------|-----|------|------|---|---------|
| Interstate | *Dest* | CA  | *    | *WR  | * | [ ] [ ] |
| Interstate | *Dest* | ID  | *    | *WR  | * | [ ] [ ] |
| Interstate | *Dest* | KS  | *    | *SCR | * | [ ] [ ] |
| Interstate | *Dest* | MO  | *    | *SCR | * | [ ] [ ] |
| Interstate | *Dest* | MT  | *    | *WR  | * | [ ] [ ] |
| Interstate | *Orig* | CA  | *    | *WR  | * |         |
| Interstate | *Orig* | ID  | *    | *WR  | * |         |
| Interstate | *Orig* | KS  | *    | *SCR | * |         |
| Interstate | *Orig* | MO  | *    | *SCR | * |         |
| Interstate | *Orig* | MT  | *    | *WR  | * |         |
| Release    | *      | ID  | *    | 1*WR | * | [ ] [ ] |
- 
- |   |                |              |
|---|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database  | [ <i>ajd</i> ] | [ 1/23/04 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw  | [ <i>KLW</i> ] | [ 2/11/04 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database   | [ <i>KLW</i> ] | [ 2/17/04 ]  |
| 8. [ ] If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |                |              |



MONSANTO  
imagine  
CONFIDENTIAL



MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-33XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-10n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-33XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from the cultivar Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2004-33XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

**Monsanto Reference ID**  
2004-33XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to \_\_10,000\_pounds of wheat seed to and from each location.

### ORIGIN:

CA, ID, KS, MO, MT

### DESTINATION:

CA, ID, KS, MO, MT

### Ship From/Ship To:

#### CA

\*[ (b) (4) Imperial County/Province, CA, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C), CA, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)  
]-CBI

#### ID

\*[ (b) (4), (b) (6), (b) (7)(C) Bingham County/Province, ID, (b) (4), (b) (6), (b) (7)(C) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C), ID, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)  
]-CBI

\*[ (b) (4) Twin Falls County/Province, ID, (b) (4) USA  
CONTACT: (b) (4), (b) (6), (b) (7)(C), ID, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)  
]-CBI

#### KS

\*[ (b) (4)  
Riley County/Province, KS, (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-33XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Pottawattamie County/Province, KS, (b) (4)  
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

MO

\* (b) (4) St. Louis County/Province, MO,  
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MT

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-33XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1)

**ID**

1 (b) (4), (b) (6), (b) (7)(C) Bingham County/Province, ID (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.  
(b) (4), (b) (6), (b) (7)(C)

**RESPONSIBLE PERSON/RESEARCHER**

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI



MONSANTO



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-33XRAB

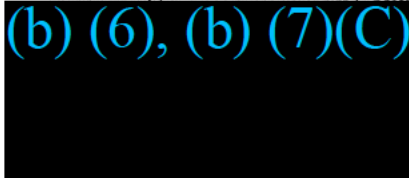
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-33XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-10n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-33XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from the cultivar Bobwhite



## *CBI-DELETED*

### **Monsanto Reference ID**

2004-33XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds. Ship up to \_\_10,000\_\_ pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, ID, KS, MO, MT

#### **DESTINATION:**

CA, ID, KS, MO, MT

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **ID**

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

[ CBI Deleted ] -- \*Twin Falls County/Province, ID, USA

##### **KS**

[ CBI Deleted ] -- \*Riley County/Province, KS, USA

[ CBI Deleted ] -- \*Pottawattamie County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1)

**ID**

[ CBI Deleted ] -- Bingham County/Province, ID, USA, 10 acres.



MONSANTO



*CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

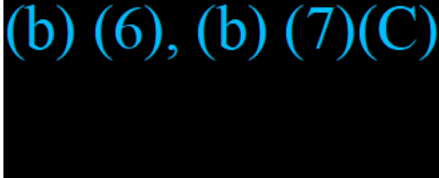
**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



MONSANTO



*CBI-DELETED*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-33XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-10n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-33XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

**Cultivar(s)/Variety(ies):** Lines derived from the cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds. Ship up to \_\_10,000\_\_ pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, ID, KS, MO, MT

#### **DESTINATION:**

CA, ID, KS, MO, MT

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **ID**

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

[ CBI Deleted ] -- \*Twin Falls County/Province, ID, USA

##### **KS**

[ CBI Deleted ] -- \*Riley County/Province, KS, USA

[ CBI Deleted ] -- \*Pottawattamie County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA



*CBI-DELETED*

**Monsanto Reference ID**  
2004-33XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID(1)

**ID**

[ CBI Deleted ] -- Bingham County/Province, ID, USA, 10 acres.



MONSANTO



*CBI-DELETED*

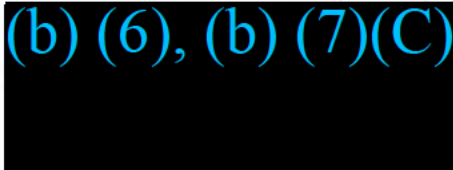
**Monsanto Reference ID**  
2004-33XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



file copy

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011040



file copy

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

January 21, 2004

Dear Mr. Cooper:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011041



file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011042



file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011043



file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:


Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011044





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature:

(b) (6), (b) (7)(C)

Date: February 4, 2004

State: California

Rptloc01/R4





California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 04-015-10N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Idaho and Kansas, shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael E. Cooper, Chief  
Bureau of Feeds & Plant Services  
Idaho State Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

January 21, 2004

RECEIVED

JAN 30 2004

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Cooper

Signature: (b) (6), (b) (7)(C)

Date: 1/31/04

State: Idaho

Rptloc01/R4







United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-10n	Applicant #:	2004-33XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO MT		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/2/04

State: Montana

Rptloc01/R4





February 11, 2004

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2004.

**Interstate movement and Release**

Notification no. 04-015-10n (2004-33XRAB)

Regulated article - Wheat

Destinations - California, Idaho, Kansas, Missouri, Montana

**This acknowledgment letter must be provided to all cooperators.**

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

181

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Cooper, Idaho State Dept. of Agric., Boise, ID  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT  
File number 04-015-10n

OR120018\_BR\_011049



California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 04-015-10N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Idaho and Kansas, shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.



# Confirmation Report-Memory Send

Time : Feb-11-04 05:29pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 909  
Date : Feb-11 05:28pm  
To : 916367377085  
Document Pages : 02  
Start time : Feb-11 05:28pm  
End time : Feb-11 05:29pm  
Pages sent : 02  
Job number : 909

\*\*\* SEND SUCCESSFUL \*\*\*



Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

February 11, 2004

(b) (6), (b) (7)(C)

700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2004.

Interstate movement and Release  
Notification no. 04-015-10n (2004-33XKAB)  
Regulated article - wheat  
Destinations - California, Idaho, Kansas, Missouri, Montana

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:  
S. Brown, California Dept. of Food and Agric., Sacramento, CA  
M. Cooper, Idaho State Dept. of Agric., Boise, ID  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_011051



*CONFIDENTIAL*

**2004 Wheat Field Test Report**

**USDA #04-015-10n**

**Monsanto #2004-33XRAB**

**February 16, 2005**

**Biotech Field Compliance Team  
Monsanto Company**

Location  
2147317251

County  
Bingham

State  
ID

Bingham County/ID (2147317251)

(b) (4)

2/17/05



(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



*CBI-DELETED*

**2004 Wheat Field Test Report**

**USDA #04-015-10n**

**Monsanto #2004-33XRAB**

**February 16, 2005**

**Biotech Field Compliance Team  
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317251	Bingham	ID

**Bingham County/ID (2147317251)**

**Planting Date:** 04/14/2004

**Destruct Date:** 07/01/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



1/21/04 2:37 pm

Notification Tracking Sheet

=====  
Bp number: 04-015-11n  
=====

App number: 2004-34XRAB  
Received: 1/15/04  
Institution: Monsanto  
Recipient: Wheat  
Status: Pending  
Effective date: 2/14/04  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: **(b) (6), (b) (7)(C)**  
Parsed name:  
Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway North  
Address3:  
Address4:  
City/State/Zip: St. Louis, MO 63198  
Telephone: **(b) (6), (b) (7)(C)**  
Fax: 636-737-7085

- |  | Initial          | Date          |
|--|------------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry       | [ <i>ajd</i> ]   | [ 1/22/04 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist                     | [ <i>ymt</i> ] * | [ 1/23/04 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [ <i>KLW</i> ]   | [ 1/29/04 ] * |
| 4. <input type="checkbox"/> State response   |                  |               |

- |            | O/d    | Loc | Site | Reg  |   |     |
|------------|--------|-----|------|------|---|-----|
| Interstate | *Dest* | CA  | *    | *WR  | * | [ ] |
| Interstate | *Dest* | KS  | *    | *SCR | * | [ ] |
| Interstate | *Dest* | MO  | *    | *SCR | * | [ ] |
| Interstate | *Dest* | MT  | *    | *WR  | * | [ ] |
| Interstate | *Orig* | CA  | *    | *WR  | * |     |
| Interstate | *Orig* | KS  | *    | *SCR | * |     |
| Interstate | *Orig* | MO  | *    | *SCR | * |     |
| Interstate | *Orig* | MT  | *    | *WR  | * |     |
| Release    | *      | *MT | *    | 3*WR | * | [ ] |
- 
- |  |                |               |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ <i>ajd</i> ] | [ 1/23/04 ]   |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw   | [ <i>KLW</i> ] | [ 2/11/04 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ <i>KLW</i> ] | [ 2/17/04 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify |                |               |



MONSANTO  
imagine  
CONFIDENTIAL



MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-34XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-11n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-34XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite



## CONFIDENTIAL

**Monsanto Reference ID**  
2004-34XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



# CONFIDENTIAL

**Monsanto Reference ID**  
2004-34XRAB

## 7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

## 8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to \_10,000\_pounds of wheat seed to and from each location.

### ORIGIN:

CA, KS, MO, MT

### DESTINATION:

CA, KS, MO, MT

### Ship From/Ship To:

CA

\* [REDACTED] (b) (4), Imperial County/Province, CA, (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) CA, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)  
J-CBI

KS

\* [REDACTED] (b) (4)  
Riley County/Province, KS (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
J-CBI

\* [REDACTED] (b) (4) Pottawattamie County/Province, KS, (b) (4) USA  
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)  
J-CBI

MO

\* [REDACTED] (b) (4) St. Louis County/Province, MO,



*CONFIDENTIAL*

Monsanto Reference ID  
2004-34XRAB

(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
(b) (4), (b) (6), (b) (7)(C) USA

] -CBI

MT

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Pondera County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Cascade County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,  
(b) (4), (b) (6), (b) (7)(C)

] -CBI

\* (b) (4) Gallatin County/Province, MT, (b) (4) USA



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-34XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI



*CONFIDENTIAL*

**Monsanto Reference ID**  
2004-34XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(3)

MT

(b) (4) Gallatin County/Province, MT, (b) (4) USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Pondera County/Province, MT, (b) (4) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Gallatin County/Province, MT, (b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI





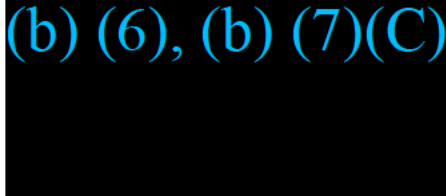
**Monsanto Reference ID**  
2004-34XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



## **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to



providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.





CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

**Monsanto Reference ID**  
2004-34XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-11n

**1. USDA Reference Number**

**2. Application Reference Number** 2004-34XRAB

**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

**4. Duration of Introduction**

Interstate Movement and Release

February 13, 2004 - February 13, 2005

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-34XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

### **GENE OF INTEREST**

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

### **GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



## *CBI-DELETED*

**Monsanto Reference ID**  
2004-34XRAB

### **7. Mode of Transformation**

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

### **8. Introduction** Interstate Movement and Release

10,000 pounds. Ship up to \_10,000\_pounds of wheat seed to and from each location.

#### **ORIGIN:**

CA, KS, MO, MT

#### **DESTINATION:**

CA, KS, MO, MT

#### **Ship From/Ship To:**

##### **CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

##### **KS**

[ CBI Deleted ] -- \*Riley County/Province, KS, USA

[ CBI Deleted ] -- \*Pottawattamie County/Province, KS, USA

##### **MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

##### **MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

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*CBI-DELETED*

**Monsanto Reference ID**  
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**NUMBER OF STATES/TERRITORIES AND SITES:**

MT(3)

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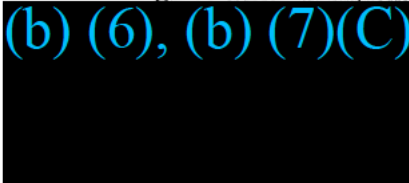
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(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004





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700 Chesterfield Parkway West

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Wheat, Triticum aestivum

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### **GENE OF INTEREST**

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**CBI**

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MONSANTO  
imagine



*CBI-DELETED*

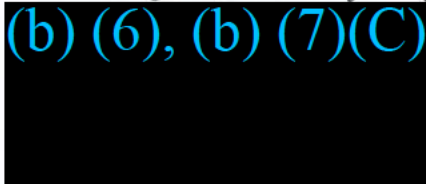
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(b) (6), (b) (7)(C)



Monsanto Company

January 14, 2004



file copy

Mr. Stephen Brown  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

January 21, 2004

Dear Mr. Brown:


Enclosed is notification 04-015-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-11n	Applicant #:	2004-34XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011077





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_011078





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

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STATE RESPONSE TO NOTIFICATION

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Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_011079



file copy

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:


Enclosed is notification 04-015-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat
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Sincerely,

  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_011080





United States  
Department of  
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Animal and  
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(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. provided all applicable quarantine requirements are met (see attached).  
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: February 4, 2004

State: California

Rpt10c01/R4







United States  
Department of  
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4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Ms. Lori Witham  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-015-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-11n Applicant #: 2004-34XRAB  
Received: January 15, 2004 Effective: February 14, 2004  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CA KS MO MT  
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/2/04

State: Montana

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_011082

FEB 2 2004



February 11, 2004

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2004.

Interstate movement and Release  
Notification no. 04-015-11n (2004-34XRAB)  
Regulated article - Wheat  
Destinations - California, Kansas, Missouri, Montana

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Regulatory Division  
Biotechnology Regulatory Services

Enclosure

cc:

S. Brown, California Dept. of Food and Agric., Sacramento, CA  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
L. Witham, Montana Dept. of Agric., Helena, MT

File number 04-015-11n

OR120018\_BR\_011083



California Quarantine Requirements  
USDA/APHIS Biotechnology Notification No. 04-015-11N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Kansas and Montana shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.
2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.



MONSANTO



MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

**NO CBI**

May 17, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

<u>USDA</u>	<u>Monsanto#</u>
04-015-11n	2004-34XRAB
04-015-14n	2004-40XRAB
04-043-09n	2004-278XRAB
04-044-02n	2004-280XRAB
04-054-05n	2004-293XRAB
04-054-06n	2004-295XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)  
Sincerely yours,

(b) (6), (b) (7)(C)

5/18/05 apl

OR120018\_BR\_011085



**CONFIDENTIAL**

**2004 Wheat Field Test Report**  
**USDA #04-015-11n**      **Monsanto #2004-34XRAB**

**May 17, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147316016	Gallatin	MT	Not Planted
2147314639	Pondera	MT	
2147303789	Gallatin	MT	

Pondera County/MT (2147314639)

(b) (4)



(b) (4)

Gallatin County/MT (2147303789)

(b) (4)



## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.



### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO



MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

NO CBI

May 17, 2005

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

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04-054-05n	2004-293XRAB
04-054-06n	2004-295XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

5/18/05 *apl*

OR120018\_BR\_011090



***CBI-DELETED***

**2004 Wheat Field Test Report**  
**USDA #04-015-11n                      Monsanto #2004-34XRAB**

**May 17, 2005**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147316016	Gallatin	MT	Not Planted
2147314639	Pondera	MT	
2147303789	Gallatin	MT	

**Pondera County/MT (2147314639)**

**Planting Date:** 04/14/2004

**Destruct Date:** 05/27/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Gallatin County/MT (2147303789)**

**Planting Date:** 04/12/2004

**Destruct Date:** 06/06/2004

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]



• **Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]